

US3572199 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

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US3572199

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Participant ID

US3572199

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

US3572199

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SCRN

US3572199

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	35
Age Units	YEARS
Age (Derived)	35
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) 22 Mar 2021 03:38:21

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Date of Informed Consent (<i>dd MMM yyyy</i>)	4 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:38:21

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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) 22 Mar 2021 03:38:21

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Condition	ULCERATIVE COLITIS
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	09 JAN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	09 JAN 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:08
Height (xxx.x)	63 in
Weight (xxx.x)	130.2 lb
BMI (xxx.x)	23.11212 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) 22 Mar 2021 03:38:21

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 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) 22 Mar 2021 03:38:21

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Date of assessment (dd MMM yyyy) 4 SEP 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) 9 JAN 2015

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: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:38:21

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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) 22 Mar 2021 03:38:21

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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) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111879

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) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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)	4 SEP 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:25
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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)	4 SEP 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:40

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) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	14:31 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:31

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:33	4 SEP 2020 14:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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 08:19:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:16

PC Open Date & Time

04 SEP 2020 15:00

PC Close Date & Time

04 SEP 2020 17:30

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	04 SEP 2020 18:28
PC Open Date & Time	04 SEP 2020 18:25
PC Close Date & Time	05 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

96.1 °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

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:29

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 15:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

04 SEP 2020 15:17

PC Open Date & Time

04 SEP 2020 15:00

PC Close Date & Time

04 SEP 2020 17:30

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

04 SEP 2020 18:28

PC Open Date & Time

04 SEP 2020 18:25

PC Close Date & Time

05 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

06 SEP 2020 12:29

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

08 SEP 2020 12:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

09 SEP 2020 12:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

10 SEP 2020 15:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:18
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PC Open Date & Time	04 SEP 2020 15:00
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PC Close Date & Time	04 SEP 2020 17:30
----------------------	-------------------

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 18:29
PC Open Date & Time	04 SEP 2020 18:25
PC Close Date & Time	05 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

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)

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:30
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:03
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:06
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:33
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3572199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	VISIT2

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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)	5 OCT 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 08:47
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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)	5 OCT 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 09:40
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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) 5 OCT 2020

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 5 OCT 2020 09:10

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

What was the frequency of the study treatment dosing? ONCE

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

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	5 OCT 2020 08:55

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)			5 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:38	5 OCT 2020 08:38
Nasopharyngeal Swab 2	No		

US3572199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 09:42

PC Open Date & Time

05 OCT 2020 09:30

PC Close Date & Time

05 OCT 2020 12:00

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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 95.9 °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	05 OCT 2020 15:06
PC Open Date & Time	05 OCT 2020 12:55
PC Close Date & Time	06 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 14:00

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

07 OCT 2020 12:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 12:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 12:01

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

05 OCT 2020 09:42

PC Open Date & Time

05 OCT 2020 09:30

PC Close Date & Time

05 OCT 2020 12:00

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

05 OCT 2020 15:06

PC Open Date & Time

05 OCT 2020 12:55

PC Close Date & Time

06 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

06 OCT 2020 14:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

07 OCT 2020 12:01

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

08 OCT 2020 12:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

09 OCT 2020 12:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

10 OCT 2020 12:01

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

11 OCT 2020 12:03

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 09:43
PC Open Date & Time	05 OCT 2020 09:30
PC Close Date & Time	05 OCT 2020 12:00

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 15:07
PC Open Date & Time	05 OCT 2020 12:55
PC Close Date & Time	06 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

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 ☒

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EAB) (1725)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 14:01
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

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)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:01
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:02
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

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)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

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)

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

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 VOICEMAIL FOR DAY 36
SAFETY CALL 10:08AM

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 NOV 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 10:10
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)	60 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)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

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

US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 NOV 2020
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	4 NOV 2020 10:30

US3572199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:16:21

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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	04 NOV 2020 11:07:05
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 09:16:34

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:02:17

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	23 NOV 2020 16:15:43
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 13:17:53
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 00:02:08
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:08:54

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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



Date and time of submission	20 DEC 2020 01:58:54
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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



Date and time of submission	27 DEC 2020 02:25:08
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 JAN 2021 00:15:18
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

24 JAN 2021 06:54:48

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

31 JAN 2021 05:21:37

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 03:15:58

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 18:53:43
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

22 FEB 2021 13:56:38

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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	01 MAR 2021 09:15:24
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:04:44

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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	14 MAR 2021 00:03:05
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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	21 MAR 2021 00:01:24
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

30 MAR 2021 10:54:20

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

04 APR 2021 00:35:03

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

11 APR 2021 00:34:25

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

18 APR 2021 00:01:28

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

25 APR 2021 00:02:12

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

03 MAY 2021 08:57:57

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 250

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

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

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

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

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

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

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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03 MAR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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24 MAR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	27 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	31 JUL 2022 00:01
Patient Cloud Close Date & Time	04 AUG 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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="checkbox"/> Yes <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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>
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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please contact your study clinic immediately. Click below to confirm that you have read this 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	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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 <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"/>

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3572199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:19:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 09:15:05

US3572199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:18:52

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:18:52

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:50
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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.

US3572199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:50

US3572199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:01:33

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:01:33

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

Date of Contact	19 DEC 2020
Time of Contact	12:00
Date and Time of Contact (derived)	19 DEC 2020 12:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

	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	19 DEC 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

	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"/>

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

Date of Visit 19 DEC 2020

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

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

Date of Test 19 DEC 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed LAREDO MEDICAL CENTER
LABORATORY

CLIA Certified? Yes ☒
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:11:37

Generated On: 10 Jun 2021 08:19:26

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Date of Contact	29 DEC 2020
Time of Contact	13:10
Date and Time of Contact (derived)	29 DEC 2020 13:10
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	12 DEC 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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"/>

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	13 DEC 2020
------	-------------

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

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

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

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

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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 checked="" 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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	14 DEC 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	15 DEC 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	16 DEC 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	17 DEC 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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	18 DEC 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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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	19 DEC 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"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

	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 checked="" 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 checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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"/>

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 10:11:36

Generated On: 10 Jun 2021 08:19:26

Date of Visit	29 DEC 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	29 DEC 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

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	1 JAN 2021
Day 5	Yes	3 JAN 2021
Day 7	Yes	5 JAN 2021
Day 9	Yes	7 JAN 2021
Day 14	Yes	12 JAN 2021
Day 21	No	19 JAN 2021
Day 28	Yes	3 FEB 2021

US3572199

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:16

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 DEC 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	29 DEC 2020 15:27
Height (xxx.x)	63 in
Weight (xxx.x)	120 lb
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572199

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:16

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 DEC 2020

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

US3572199

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 04:45:16

Generated On: 10 Jun 2021 08:19:26

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 DEC 2020

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	17:40 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 17:40
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

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

US3572199

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 04:45:15

Generated On: 10 Jun 2021 08:19:26

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

3 FEB 2021

US3572199

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 FEB 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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US3572199

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Date of updated informed consent (<i>dd MMM yyyy</i>)	02 FEB 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>)	02 FEB 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

US3572199

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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

US3572199

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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)	03 FEB 2021
Time of assessment (00:00-23:59)	17:40 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 17:40
Temperature (xxx.x)	98.1 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)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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)	03 FEB 2021
Time of assessment (00:00-23:59)	19:17 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 19:17
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 FEB 2021

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

US3572199

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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) 03 FEB 2021

What was the treatment time? (00:00-23:59) 18:47 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 18:47

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

US3572199

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00-23:59)	14:47 (24 HR)
Collection date and time (derived)	02 FEB 2021 14:47

US3572199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	14:38
Collection Date and Time (derived)	02 FEB 2021 14:38

US3572199

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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)	10 MAR 2021
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 15:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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)	10 MAR 2021
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 15:55
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	TRMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3572199

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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.

US3572199

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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) 10 MAR 2021

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 10 MAR 2021 15:25

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

US3572199

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572199

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:48
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572199

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

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.

US3572199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:45:30

Generated On: 10 Jun 2021 08:19:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:50

US3572199

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

AEID

Adverse event

SCRATCH TO RIGHT EYE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 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 (1)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

AEID	USA-US091-2020-MRNA-1273-P30 1000008
Adverse event	WORSENING OF COLITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input 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)	12 DEC 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)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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	True
Hospital Admission Date (dd MMM yyyy)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	PENDING ADDITIONAL MEDICAL RECORDS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

AEID	USA-US091-2020-MRNA-1273-P30 1000008
Adverse event	COVID-19 POSITIVE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 DEC 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)	07 JAN 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 checked="" 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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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	SOURCE SHOWS SUBJECT TESTED POSITIVE FOR COVID-19 ON 19DEC20
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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 type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:14:57

Generated On: 10 Jun 2021 08:19:26

Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with <input type="checkbox"/>
	Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

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

Yes ☒

No ☐

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

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	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)	24 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 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"/>

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication GENTAMICIN EYE DROPS

Prophylaxis Yes ☐
No ☒

Indication SCRATCH TO RIGHT EYE

Dose per administration 1

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

If dose unit is Other, specify DROP TO AFFECTED EYE

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

If frequency is Other, specify

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

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EAB) (1725)

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US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication LOPERAMIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE HEMORRHAGIC COLITIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HRS AS NEEDED

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	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)	19 DEC 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 POSITIVE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	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)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication COLITIS/DIARRHEA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	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)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

	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 UNK 2017	
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"/>

US3572199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:45:15

Generated On: 10 Jun 2021 08:19:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3572199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:19:26

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

US3572199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:19:26

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 ☐

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	31/DEC/2020 13:36
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	04/JAN/2021 15:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	06/JAN/2021 14:16
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:29
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	17/FEB/2021 14:07
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	17/FEB/2021 14:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	05/MAR/2021 14:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	17/MAR/2021 16:12
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:27
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (10)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:27
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

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (11)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	31/MAR/2021 13:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (12)

Data signed: (b) (4) 11 Apr 2021 07:10:39

Generated On: 10 Jun 2021 08:19:26

SAEID	USA-US091-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12
Date of submission (Pre-filled from custom function)	09/APR/2021 10:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572199 (Prod: Laguna Clinical Research Associates)

US3572199

Form: Participant Creation

Generated On: 10 Jun 2021 08:19:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:37:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'US3572199'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:51

US3572199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:26:57
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1 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)	09 Dec 2020 04:29:40
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1 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 'LAB UPDATED DATA' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:46:21
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1 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 04:35:36
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:05

US3572199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:26:57
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:52

US3572199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:26:57
User entered 'Clinic (Clinic)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:05

US3572199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'SCRN'	System	04 Sep 2020 19:45:05

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:53

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '35'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'YEARS'	System	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '35'	System	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered 'Female (F)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered 'l'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered empty.	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:09
User entered '0'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:28

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered '4 Sep 2020'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'Sep 2020'	System	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '2020'	System	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered 'Amendment 3 (3)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered empty.	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered empty.	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:45:56

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:52

US3572199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'l'	System	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:38
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:19:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:27:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:08:52

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:15:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:15:31
Data point term sent to Coder	System	15 Oct 2020 18:14:16
User entered 'ULCERATIVE COLITIS'	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered 'un UNK 2011'	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'Jan 2011'	System	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '2011'	System	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered empty.	System	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered empty.	System	15 Oct 2020 18:13:53

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 15:28:01
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:41:41
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:25:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:16:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:16:29
Data point term sent to Coder	System	15 Oct 2020 18:15:17
User entered 'BILATERAL TUBAL LIGATION'	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '09 Jan 2015'	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:14:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 18:14:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:14:42
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:14:36
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '09 Jan 2015'	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:01
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'Jan 2015'	System	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '2015'	System	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'Jan 2015'	System	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '2015'	System	15 Oct 2020 18:14:36

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:00:15
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:03:22
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:44:19
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered '14:08'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '4 Sep 2020 14:08'	System	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 05:02:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '63' in	(b) (4), (b) (6)	08 Dec 2020 16:43:15
DataPoint set to visible.	System	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered '130.2' lb reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 05:02:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '130.2' lb	(b) (4), (b) (6)	08 Dec 2020 16:43:15
DataPoint set to visible.	System	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered '23.11212'	System	05 Jan 2021 05:02:43
User entered empty.	System	05 Jan 2021 04:59:04
User entered '23.11212'	System	08 Dec 2020 16:43:15
DataPoint set to visible.	System	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'kg/m2'	System	05 Jan 2021 05:02:43
User entered empty.	System	05 Jan 2021 04:59:04
User entered 'kg/m2'	System	08 Dec 2020 16:43:15
DataPoint set to visible.	System	04 Sep 2020 19:46:05

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '97.2' F	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '65'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'bpm'	System	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'breaths/min'	System	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '118'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'mmHg'	System	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 04:59:04
User entered '80'	(b) (4), (b) (6)	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User entered 'mmHg'	System	08 Dec 2020 16:43:15

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30

US3572199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30

US3572199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:43:30

US3572199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:25
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:43:30

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	08 Dec 2020 16:45:14
User opened query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	08 Dec 2020 16:45:01
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	08 Dec 2020 16:45:01
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:45:01
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	08 Dec 2020 16:44:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:45:14
User entered 'TUBAL LIGATION 09JAN2015'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered '9 Jan 2015'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:26

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:35
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:44:49

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered 'l'	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:30
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:12
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:46:02

US3572199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:37:16

US3572199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:17
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:37:16

US3572199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Dec 2020 16:37:16

US3572199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'VISIT1'	System	08 Dec 2020 16:37:16

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:29:37

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered '111879'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:29:37

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:29:37

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55

US3572199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:29:34
User closed query 'Per CDM please complete the missing data on this form. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:10:31
Query 'Per CDM please complete the missing data on this form. ' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:38:02
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:37:55
User opened query 'Per CDM please complete the missing data on this form. ' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 22:05:15
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:29:07

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4)	
Query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:04:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:36:09
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:19
User opened query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '63' in	(b) (4), (b) (6)	07 Jan 2021 15:30:58
	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:36:01
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '130.2' lb	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4)	
Query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:04:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:36:09
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:19
User opened query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '63' in	(b) (4), (b) (6)	07 Jan 2021 15:30:58
	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:01
	(b) (4), (b) (6)	07 Jan 2021 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '130.2' lb	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per source, 1425 is noted. Please reconcile.' (Site from CRA).	(b) (4)	
Query 'Per source, 1425 is noted. Please reconcile.' answered with 'reconciled per source' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 09:46:55
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:53
User entered '14:25' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:36:36
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User opened query 'Per source, 1425 is noted. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:30:21
User entered '14:08'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered '4 Sep 2020 14:25'	System	27 Jan 2021 07:36:36
User entered '4 Sep 2020 14:08'	System	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '97.2' F	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '65'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'bpm'	System	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'breaths/min'	System	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '118'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'mmHg'	System	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '80'	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'mmHg'	System	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4)	
Query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:04:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:36:09
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:01
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:19
User opened query 'Per edc guidelines, height and weight are entered at screening. Please confirm/remove these entries.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '63' in	(b) (4), (b) (6)	07 Jan 2021 15:30:58
	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:02
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 07:36:01
	(b) (4), (b) (6)	07 Jan 2021 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '130.2' lb	(b) (4), (b) (6)	08 Dec 2020 16:39:14

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '15:10'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered '4 Sep 2020 15:10'	System	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '97.3' F	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '57'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'bpm'	System	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'breaths/min'	System	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '118'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'mmHg'	System	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User entered '79'	(b) (4), (b) (6)	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'mmHg'	System	08 Dec 2020 16:41:16

US3572199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per edc guidelines, PE is entered at screening. Please remove entry.' (Site from CRA).	(b) (4)	
Query 'Per edc guidelines, PE is entered at screening. Please remove entry.' answered with 'updated per query' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 18:04:53
	(b) (4), (b) (6)	27 Jan 2021 07:35:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 07:35:14
User opened query 'Per edc guidelines, PE is entered at screening. Please remove entry.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:31:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:41:29

US3572199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:04:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 07:35:14
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:41:29

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 04Sep2020 is reported under Visit 1 Day 1 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)	09 Dec 2020 07:07:53
User closed query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 04SEP2020 however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:07:44
Query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 04SEP2020 however the same is missing in EDC. Please add or clarify' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:46:50
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 04Sep2020 is reported under Visit 1 Day 1 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 'LAB UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:46:38
User opened query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 04SEP2020 however the same is missing in EDC. Please add or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:35:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 04Sep2020 is reported under Visit 1 Day 1 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 08:29:34
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered empty.	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered empty.	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered '4 Sep 2020'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered '14:40'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered '4 Sep 2020 14:40'	System	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:32:08
User entered 'ONCE'	System	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 19:47:15

US3572199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:41:52

US3572199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 1Day 01 sample with Accession # 1F602697932. Per response if 08 SEP 2020 was not collected for this subject then please review the Accession # 1F602697932 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs to? Thank you' (Site from DM).	(b) (4) (u) (4), (b) (6)	03 Mar 2021 07:50:23
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 1Day 01 sample with Accession # 1F602697932. Per response if 08 SEP 2020 was not collected for this subject then please review the Accession # 1F602697932 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs to? Thank you' answered with 'Accession # 1F60GBK collection date 04Sep2020 US3572199 ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:43:50
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 1Day 01 sample with Accession # 1F602697932. Per response if 08 SEP 2020 was not collected for this subject then please review the Accession # 1F602697932 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs to? Thank you' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:25:33
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:25:33

US3572199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate.' answered with 'lab sample was collected on 04Sep2020 for V1D1, no sample was collected on 08Sep2020' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 19:16:51
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:44:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:32:18
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:41:52

US3572199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:18
User entered '14:31'	(b) (4), (b) (6)	08 Dec 2020 16:41:52

US3572199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered '4 Sep 2020 14:31'	System	08 Dec 2020 16:41:52

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here in EDC is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:02:30
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here in EDC is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4), (b) (6)	02 Feb 2021 19:16:23
' answered with 'Swab was collected on 04Sep2020 for V1D1, no sample was collected on 08Sep2020' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 08SEP2020 for the Visit 1 Day 1 Visit, however, the Collection Date recorded here in EDC is 04SEP2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4), (b) (6)	28 Jan 2021 07:23:22
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:32:23
User entered '4 Sep 2020'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:23
User entered '14:33'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered '4 Sep 2020 14:33'	System	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:23
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered empty.	System	08 Dec 2020 16:42:13

US3572199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:27
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:12:33

US3572199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:53:35
User entered 'I'	System	18 Sep 2020 19:12:33

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:16:19', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f2da65fc-ccdd-4d5f-bea8-896c2ba40f3c'	System	04 Sep 2020 20:16:43
User entered 'Yes (Y)'	System	04 Sep 2020 20:16:43

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:16:25', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f2da65fc-ccdd-4d5f-bea8-896c2ba40f3c'	System	04 Sep 2020 20:16:43
User entered '97.3'	System	04 Sep 2020 20:16:43

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:16:31', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f2da65fc-ccdd-4d5f-bea8-896c2ba40f3c'	System	04 Sep 2020 20:16:43
User entered 'No (N)'	System	04 Sep 2020 20:16:43

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:16:40', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f2da65fc-ccdd-4d5f-bea8-896c2ba40f3c'	System	04 Sep 2020 20:16:43
User entered '04 Sep 2020 15:16'	System	04 Sep 2020 20:16:43

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '04 Sep 2020 15:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '04 Sep 2020 17:30'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5a356205-12ab-4183-8198-5044f660e9cc'	System	04 Sep 2020 23:28:25
User entered 'Yes (Y)'	System	04 Sep 2020 23:28:25

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5a356205-12ab-4183-8198-5044f660e9cc'	System	04 Sep 2020 23:28:25
User entered '97.6'	System	04 Sep 2020 23:28:25

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5a356205-12ab-4183-8198-5044f660e9cc'	System	04 Sep 2020 23:28:25
User entered 'No (N)'	System	04 Sep 2020 23:28:25

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5a356205-12ab-4183-8198-5044f660e9cc'	System	04 Sep 2020 23:28:25
User entered '04 Sep 2020 18:28'	System	04 Sep 2020 23:28:25

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '04 Sep 2020 18:25'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 2'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:01:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '98feef68-c2fb-4f7a-8a46-f773fb271a70'	System	05 Sep 2020 17:02:42
User entered 'Yes (Y)'	System	05 Sep 2020 17:02:42

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '98feef68-c2fb-4f7a-8a46-f773fb271a70'	System	05 Sep 2020 17:02:42
User entered '96.1'	System	05 Sep 2020 17:02:42

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:26', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '98feef68-c2fb-4f7a-8a46-f773fb271a70'	System	05 Sep 2020 17:02:42
User entered 'No (N)'	System	05 Sep 2020 17:02:42

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:33', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '98feef68-c2fb-4f7a-8a46-f773fb271a70'	System	05 Sep 2020 17:02:42
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:42

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 3'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:28:25', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f79cb0d6-442a-46b2-bf39-572201ffe3c5'	System	06 Sep 2020 17:29:34
User entered 'Yes (Y)'	System	06 Sep 2020 17:29:34

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:23', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f79cb0d6-442a-46b2-bf39-572201ffe3c5'	System	06 Sep 2020 17:29:34
User entered '96.7'	System	06 Sep 2020 17:29:34

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:27', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f79cb0d6-442a-46b2-bf39-572201ffe3c5'	System	06 Sep 2020 17:29:34
User entered 'No (N)'	System	06 Sep 2020 17:29:34

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:32', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f79cb0d6-442a-46b2-bf39-572201ffe3c5'	System	06 Sep 2020 17:29:34
User entered '06 Sep 2020 12:29'	System	06 Sep 2020 17:29:34

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 4'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:01:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ed4a4019-180a-4296-8301-7e9aad7f9eb2'	System	07 Sep 2020 17:02:22
User entered 'Yes (Y)'	System	07 Sep 2020 17:02:22

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ed4a4019-180a-4296-8301-7e9aad7f9eb2'	System	07 Sep 2020 17:02:22
User entered '97.0'	System	07 Sep 2020 17:02:22

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:10', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ed4a4019-180a-4296-8301-7e9aad7f9eb2'	System	07 Sep 2020 17:02:22
User entered 'No (N)'	System	07 Sep 2020 17:02:22

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ed4a4019-180a-4296-8301-7e9aad7f9eb2'	System	07 Sep 2020 17:02:22
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 17:02:22

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 5'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:01:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7235f7e7-870d-468e-834e-fc6b189e2912'	System	08 Sep 2020 17:04:02
User entered 'Yes (Y)'	System	08 Sep 2020 17:04:02

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:31', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7235f7e7-870d-468e-834e-fc6b189e2912'	System	08 Sep 2020 17:04:02
User entered '97.1'	System	08 Sep 2020 17:04:02

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7235f7e7-870d-468e-834e-fc6b189e2912'	System	08 Sep 2020 17:04:02
User entered 'No (N)'	System	08 Sep 2020 17:04:02

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:37', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7235f7e7-870d-468e-834e-fc6b189e2912'	System	08 Sep 2020 17:04:02
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 17:04:02

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 6'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '38e9c1fa-f8e7-4cef-bfd1-bd3883cabb55'	System	09 Sep 2020 17:05:49
User entered 'Yes (Y)'	System	09 Sep 2020 17:05:49

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:19', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '38e9c1fa-f8e7-4cef-bfd1-bd3883cabb55'	System	09 Sep 2020 17:05:49
User entered '97.0'	System	09 Sep 2020 17:05:49

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:26', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '38e9c1fa-f8e7-4cef-bfd1-bd3883cabb55'	System	09 Sep 2020 17:05:49
User entered 'No (N)'	System	09 Sep 2020 17:05:49

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:29', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '38e9c1fa-f8e7-4cef-bfd1-bd3883cabb55'	System	09 Sep 2020 17:05:49
User entered '09 Sep 2020 12:05'	System	09 Sep 2020 17:05:49

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 7'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:30', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '152d4106-b31e-477d-9c90-ebc7cdca6b82'	System	10 Sep 2020 20:32:45
User entered 'Yes (Y)'	System	10 Sep 2020 20:32:45

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '152d4106-b31e-477d-9c90-ebc7cdca6b82'	System	10 Sep 2020 20:32:45
User entered '97.0'	System	10 Sep 2020 20:32:45

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '152d4106-b31e-477d-9c90-ebc7cdca6b82'	System	10 Sep 2020 20:32:45
User entered 'No (N)'	System	10 Sep 2020 20:32:45

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '152d4106-b31e-477d-9c90-ebc7cdca6b82'	System	10 Sep 2020 20:32:45
User entered '10 Sep 2020 15:32'	System	10 Sep 2020 20:32:45

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7bab6469-c038-4a21-80cc-7e79df46fa7f'	System	04 Sep 2020 20:17:48
User entered 'None (1)'	System	04 Sep 2020 20:17:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:22', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7bab6469-c038-4a21-80cc-7e79df46fa7f'	System	04 Sep 2020 20:17:48
User entered 'No (N)'	System	04 Sep 2020 20:17:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:33', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7bab6469-c038-4a21-80cc-7e79df46fa7f'	System	04 Sep 2020 20:17:48
User entered 'No (N)'	System	04 Sep 2020 20:17:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7bab6469-c038-4a21-80cc-7e79df46fa7f'	System	04 Sep 2020 20:17:48
User entered 'None (1)'	System	04 Sep 2020 20:17:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7bab6469-c038-4a21-80cc-7e79df46fa7f'	System	04 Sep 2020 20:17:48
User entered '04 Sep 2020 15:17'	System	04 Sep 2020 20:17:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 15:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 17:30'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:27', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '24b638f2-d853-4600-85ab-f0c616b06ed6'	System	04 Sep 2020 23:28:49
User entered 'None (1)'	System	04 Sep 2020 23:28:49

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:30', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '24b638f2-d853-4600-85ab-f0c616b06ed6'	System	04 Sep 2020 23:28:49
User entered 'No (N)'	System	04 Sep 2020 23:28:49

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '24b638f2-d853-4600-85ab-f0c616b06ed6'	System	04 Sep 2020 23:28:49
User entered 'No (N)'	System	04 Sep 2020 23:28:49

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '24b638f2-d853-4600-85ab-f0c616b06ed6'	System	04 Sep 2020 23:28:49
User entered 'None (1)'	System	04 Sep 2020 23:28:49

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:46', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '24b638f2-d853-4600-85ab-f0c616b06ed6'	System	04 Sep 2020 23:28:49
User entered '04 Sep 2020 18:28'	System	04 Sep 2020 23:28:49

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 18:25'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 2'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f23b31c-1242-4447-ae8c-20250ecf6c84'	System	05 Sep 2020 17:02:58
User entered 'None (1)'	System	05 Sep 2020 17:02:58

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:40', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f23b31c-1242-4447-ae8c-20250ecf6c84'	System	05 Sep 2020 17:02:58
User entered 'No (N)'	System	05 Sep 2020 17:02:58

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:47', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f23b31c-1242-4447-ae8c-20250ecf6c84'	System	05 Sep 2020 17:02:58
User entered 'No (N)'	System	05 Sep 2020 17:02:58

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f23b31c-1242-4447-ae8c-20250ecf6c84'	System	05 Sep 2020 17:02:58
User entered 'None (1)'	System	05 Sep 2020 17:02:58

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:55', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f23b31c-1242-4447-ae8c-20250ecf6c84'	System	05 Sep 2020 17:02:58
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 17:02:58

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 3'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '6efe6a6a-4155-4783-b2a6-90f5cf811e3c'	System	06 Sep 2020 17:29:48
User entered 'None (1)'	System	06 Sep 2020 17:29:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:40', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '6efe6a6a-4155-4783-b2a6-90f5cf811e3c'	System	06 Sep 2020 17:29:48
User entered 'No (N)'	System	06 Sep 2020 17:29:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '6efe6a6a-4155-4783-b2a6-90f5cf811e3c'	System	06 Sep 2020 17:29:48
User entered 'No (N)'	System	06 Sep 2020 17:29:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '6efe6a6a-4155-4783-b2a6-90f5cf811e3c'	System	06 Sep 2020 17:29:48
User entered 'None (1)'	System	06 Sep 2020 17:29:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:47', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '6efe6a6a-4155-4783-b2a6-90f5cf811e3c'	System	06 Sep 2020 17:29:48
User entered '06 Sep 2020 12:29'	System	06 Sep 2020 17:29:48

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 4'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:20', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5b21f4bf-aecb-467c-b1db-8364bc3bb58f'	System	07 Sep 2020 17:02:37
User entered 'None (1)'	System	07 Sep 2020 17:02:37

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:24', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5b21f4bf-aecb-467c-b1db-8364bc3bb58f'	System	07 Sep 2020 17:02:37
User entered 'No (N)'	System	07 Sep 2020 17:02:37

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:26', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5b21f4bf-aecb-467c-b1db-8364bc3bb58f'	System	07 Sep 2020 17:02:37
User entered 'No (N)'	System	07 Sep 2020 17:02:37

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:28', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5b21f4bf-aecb-467c-b1db-8364bc3bb58f'	System	07 Sep 2020 17:02:37
User entered 'None (1)'	System	07 Sep 2020 17:02:37

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:30', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5b21f4bf-aecb-467c-b1db-8364bc3bb58f'	System	07 Sep 2020 17:02:37
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 17:02:37

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 5'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e16bba40-1073-4ea2-8cdc-a2d1edeac1e9'	System	08 Sep 2020 17:04:25
User entered 'None (1)'	System	08 Sep 2020 17:04:25

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e16bba40-1073-4ea2-8cdc-a2d1edeac1e9'	System	08 Sep 2020 17:04:25
User entered 'No (N)'	System	08 Sep 2020 17:04:25

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e16bba40-1073-4ea2-8cdc-a2d1edeac1e9'	System	08 Sep 2020 17:04:25
User entered 'No (N)'	System	08 Sep 2020 17:04:25

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:02:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e16bba40-1073-4ea2-8cdc-a2d1edeac1e9'	System	08 Sep 2020 17:04:25
User entered 'None (1)'	System	08 Sep 2020 17:04:25

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e16bba40-1073-4ea2-8cdc-a2d1edeac1e9'	System	08 Sep 2020 17:04:25
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 17:04:25

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 6'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1943912e-e5cb-4115-8df6-d6a76be45953'	System	09 Sep 2020 17:05:56
User entered 'None (1)'	System	09 Sep 2020 17:05:56

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1943912e-e5cb-4115-8df6-d6a76be45953'	System	09 Sep 2020 17:05:56
User entered 'No (N)'	System	09 Sep 2020 17:05:56

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1943912e-e5cb-4115-8df6-d6a76be45953'	System	09 Sep 2020 17:05:56
User entered 'No (N)'	System	09 Sep 2020 17:05:56

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1943912e-e5cb-4115-8df6-d6a76be45953'	System	09 Sep 2020 17:05:56
User entered 'None (1)'	System	09 Sep 2020 17:05:56

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1943912e-e5cb-4115-8df6-d6a76be45953'	System	09 Sep 2020 17:05:56
User entered '09 Sep 2020 12:05'	System	09 Sep 2020 17:05:56

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 7'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bbdb65a0-930f-4d7e-90b8-2518552bfe79'	System	10 Sep 2020 20:32:55
User entered 'None (1)'	System	10 Sep 2020 20:32:55

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:46', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bbdb65a0-930f-4d7e-90b8-2518552bfe79'	System	10 Sep 2020 20:32:55
User entered 'No (N)'	System	10 Sep 2020 20:32:55

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bbdb65a0-930f-4d7e-90b8-2518552bfe79'	System	10 Sep 2020 20:32:55
User entered 'No (N)'	System	10 Sep 2020 20:32:55

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:50', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bbdb65a0-930f-4d7e-90b8-2518552bfe79'	System	10 Sep 2020 20:32:55
User entered 'None (1)'	System	10 Sep 2020 20:32:55

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bbdb65a0-930f-4d7e-90b8-2518552bfe79'	System	10 Sep 2020 20:32:55
User entered '10 Sep 2020 15:32'	System	10 Sep 2020 20:32:55

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:17:56', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'None (0)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:11', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered 'No (N)'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T15:18:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4a47995d-389a-44ee-b407-c79fee485b4c'	System	04 Sep 2020 20:18:17
User entered '04 Sep 2020 15:18'	System	04 Sep 2020 20:18:17

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 15:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 17:30'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:56', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:28:58', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:29:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:29:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'None (0)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:29:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered 'No (N)'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-04T18:29:09', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ac82aaea-f718-47ad-9cee-7522b34593d8'	System	04 Sep 2020 23:29:13
User entered '04 Sep 2020 18:29'	System	04 Sep 2020 23:29:13

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '04 Sep 2020 18:25'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 2'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:02:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:11', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'None (0)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered 'No (N)'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-05T12:03:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'add7a1f6-409e-4905-801e-48616d2ded9f'	System	05 Sep 2020 17:03:24
User entered '05 Sep 2020 12:03'	System	05 Sep 2020 17:03:24

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 3'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:50', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:52', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:55', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:29:58', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:30:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:30:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'None (0)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:30:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered 'No (N)'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-06T12:30:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'cc5ef03e-8fc9-401a-a467-761d25f00a18'	System	06 Sep 2020 17:30:11
User entered '06 Sep 2020 12:30'	System	06 Sep 2020 17:30:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 4'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:37', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:40', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'None (0)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered 'No (N)'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-07T12:02:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '871cafca-5bc4-4efd-b95f-50267f5f7106'	System	07 Sep 2020 17:02:55
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 17:02:55

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 5'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:10', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:15', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'None (0)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered 'No (N)'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-08T12:03:20', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '67fa056f-468f-4472-b97f-209ee6fdbb75'	System	08 Sep 2020 17:04:40
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 17:04:40

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 6'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:55', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:05:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'None (0)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:06:04', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered 'No (N)'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-09T12:06:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '5df65fb7-105d-4554-a074-b4b15b456807'	System	09 Sep 2020 17:06:11
User entered '09 Sep 2020 12:06'	System	09 Sep 2020 17:06:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 7'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:55', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:58', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:32:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:33:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'None (0)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:33:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered 'No (N)'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-09-10T15:33:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f91611be-25d1-4c6d-8851-c5de8b10b051'	System	10 Sep 2020 20:33:11
User entered '10 Sep 2020 15:33'	System	10 Sep 2020 20:33:11

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:47:15

US3572199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:35
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:00
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:12:51

US3572199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:00
User entered '11 Sep 2020'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:12:51

US3572199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:00
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:12:51

US3572199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:00
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	18 Sep 2020 19:12:51

US3572199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:07
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:12:55

US3572199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:56:52
User entered 'l'	System	18 Sep 2020 19:12:55

US3572199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:23
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:13:05

US3572199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:23
User entered '18 Sep 2020'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:13:05

US3572199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:23
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:13:05

US3572199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:23
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	18 Sep 2020 19:13:05

US3572199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:26
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 19:13:11

US3572199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:16:23
User entered 'l'	System	18 Sep 2020 19:13:11

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 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) (4), (b) (6)	29 Jan 2021 05:59:24
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'EDC immunogenicity assessment is updated accordingly for Visit 2 Day 29' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 01:31:09
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:33:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:13:49
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:17:04

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-OCT-2020 is reported under Visit 2 Day 29 in PPD portal; however, the swab sample for 05-OCT-2020 is missing in EDC. Kindly confirm if swab sample was collected on 05-OCT-2020 for visit 2 Day 29, if yes, update the data as appropriate, else clarify. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-OCT-2020 is reported under Visit 2 Day 29 in PPD portal; however, the swab sample for 05-OCT-2020 is missing in EDC. Kindly confirm if swab sample was collected on 05-OCT-2020 for visit 2 Day 29, if yes, update the data as appropriate, else clarify. ' answered with 'EDC is updated accordingly for swab sample for Visit 2 Day 29' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 05:59:27
	(b) (4), (b) (6)	29 Jan 2021 01:35:17
	(b) (4), (b) (6)	07 Jan 2021 15:33:35
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-OCT-2020 is reported under Visit 2 Day 29 in PPD portal; however, the swab sample for 05-OCT-2020 is missing in EDC. Kindly confirm if swab sample was collected on 05-OCT-2020 for visit 2 Day 29, if yes, update the data as appropriate, else clarify. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-OCT-2020 is reported under Visit 2 Day 29 in PPD portal; however, the swab sample for 05-OCT-2020 is missing in EDC. Kindly confirm if swab sample was collected on 06-NOV-2020 for visit 2 Day 29, if yes, update the data as appropriate, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:34:41
	(b) (4), (b) (6)	17 Nov 2020 06:34:25
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05-OCT-2020 is reported under Visit 2 Day 29 in PPD portal; however, the swab sample for 05-OCT-2020 is missing in EDC. Kindly confirm if swab sample was collected on 06-NOV-2020 for visit 2 Day 29, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:17:16

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Reconciliation: Swab sample collected on 05OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date & also update the corresponding Swab data as it is missing in EDC.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:17:06
User opened query 'Per GCL Reconciliation: Swab sample collected on 05OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date & also update the corresponding Swab data as it is missing in EDC.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:11:54
User entered '25 Sep 2020'	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:17:04

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:35
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:17:04

US3572199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:35
User entered empty.	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:17:04

US3572199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:38
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:17:09

US3572199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:18
User entered 'l'	System	25 Sep 2020 13:17:09

US3572199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:47:48

US3572199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:40
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:47:48

US3572199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Dec 2020 16:47:48

US3572199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'VISIT2'	System	08 Dec 2020 16:47:48

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:39:57
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per source 0847 is noted. Please reconcile.' (Site from CRA).	(b) (4)	
Query 'Per source 0847 is noted. Please reconcile.' answered with 'time updated per source' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 09:48:07
DataPoint Un-verified.	(b) (4), (b) (6)	03 Feb 2021 23:51:41
User entered '08:47' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 23:50:46
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 23:50:46
	(b) (4), (b) (6)	07 Jan 2021 15:52:40
User opened query 'Per source 0847 is noted. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:52:15
User entered '08:40'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '5 Oct 2020 08:47'	System	03 Feb 2021 23:50:46
User entered '5 Oct 2020 08:40'	System	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '97.5' F	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '56'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'bpm'	System	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'breaths/min'	System	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '114'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '84'	(b) (4), (b) (6)	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:48:31

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '09:40'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '5 Oct 2020 09:40'	System	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '97.2' F	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '60'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'bpm'	System	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'breaths/min'	System	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '114'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:40
User entered '73'	(b) (4), (b) (6)	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:49:43

US3572199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:49:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:52:52
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:49:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 05OCT2020 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)	15 Dec 2020 19:33:35
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 05OCT2020 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 'updated' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 14:13:35
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 05OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:33:02
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User entered empty.	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User entered empty.	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User entered '5 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User closed query 'Per CDM: Per CCG, Time should be recorded in 24- hour clock format (HH:MM). Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:08:50
Query 'Per CDM: Per CCG, Time should be recorded in 24- hour clock format (HH:MM). Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:47:32
User entered '09:10' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 05:47:01
User opened query 'Per CDM: Per CCG, Time should be recorded in 24- hour clock format (HH:MM). Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:39:25
User entered '9:10'	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '5 Oct 2020 09:10'	System	04 Jan 2021 05:47:01
User entered '5 Oct 2020 9:10'	System	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:18
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:53:18
User entered 'ONCE'	System	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 14:23:13

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:50:23

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation requery: Antibody Mediated Immunogenicity: Per response, "per source this immunogenicity assessment matches the date and time for 12 OCT Visit 2 day 29"; however, per PPD portal, immuno samples are present for visit 2 with date 05-10-2020 & accession number "1F603097124" & date 07-10-2020 with accession number "1F619226152". Kindly review the collection date and accession number and update EDC or Preclarus Portal as appropriate, else clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	04 Mar 2021 08:48:35
Query 'Per GCL Lab Reconciliation requery: Antibody Mediated Immunogenicity: Per response, "per source this immunogenicity assessment matches the date and time for 12 OCT Visit 2 day 29"; however, per PPD portal, immuno samples are present for visit 2 with date 05-10-2020 & accession number "1F603097124" & date 07-10-2020 with accession number "1F619226152". Kindly review the collection date and accession number and update EDC or Preclarus Portal as appropriate, else clarify.' answered with 'collection date 05OCT2020 accession 1F60GBK ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:44:52
User opened query 'Per GCL Lab Reconciliation requery: Antibody Mediated Immunogenicity: Per response, "per source this immunogenicity assessment matches the date and time for 12 OCT Visit 2 day 29"; however, per PPD portal, immuno samples are present for visit 2 with date 05-10-2020 & accession number "1F603097124" & date 07-10-2020 with accession number "1F619226152". Kindly review the collection date and accession number and update EDC or Preclarus Portal as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:40:59

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:40:59
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate.' answered with 'per source this immunogenicity assessment matches the date and time for 12 OCT Visit 2 day 29' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 01:43:48
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an immunogenicity sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:43:00
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:53:27
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:50:23

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:27
User entered '08:55'	(b) (4), (b) (6)	08 Dec 2020 16:50:23

US3572199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '5 Oct 2020 08:55'	System	08 Dec 2020 16:50:23

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here in EDC is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 05:57:42
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here in EDC is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4), (b) (6)	29 Jan 2021 01:34:45
' answered with 'per source the nasopharyngeal swab was collected as date shown 05 OCT 2020' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Per PPD Central Labs, there is a Swab sample collected on 07OCT2020 for the Visit 2 Day 29 Visit, however, the Collection Date recorded here in EDC is 05OCT2020. Please confirm the correct Collection Date in the query response and update if appropriate. Thank you.	(b) (4), (b) (6)	28 Jan 2021 07:26:38
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:53:33
User entered '5 Oct 2020'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:33
User entered '08:38'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '5 Oct 2020 08:38'	System	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:33
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:33
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered empty.	System	08 Dec 2020 16:50:57

US3572199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:53:42
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:01:20

US3572199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'I'	System	13 Oct 2020 15:01:20

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:41:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '13ffeca5-2e82-4138-a0af-af41edb5cffe'	System	05 Oct 2020 14:42:11
User entered 'Yes (Y)'	System	05 Oct 2020 14:42:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:41:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '13ffeca5-2e82-4138-a0af-af41edb5cffe'	System	05 Oct 2020 14:42:11
User entered '97.2'	System	05 Oct 2020 14:42:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '13ffeca5-2e82-4138-a0af-af41edb5cffe'	System	05 Oct 2020 14:42:11
User entered 'No (N)'	System	05 Oct 2020 14:42:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '13ffeca5-2e82-4138-a0af-af41edb5cffe'	System	05 Oct 2020 14:42:11
User entered '05 Oct 2020 09:42'	System	05 Oct 2020 14:42:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 09:30'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:04:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bc37fd94-976b-4bb1-87f3-0319610d0c0d'	System	05 Oct 2020 20:06:47
User entered 'Yes (Y)'	System	05 Oct 2020 20:06:47

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bc37fd94-976b-4bb1-87f3-0319610d0c0d'	System	05 Oct 2020 20:06:47
User entered '95.9'	System	05 Oct 2020 20:06:47

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bc37fd94-976b-4bb1-87f3-0319610d0c0d'	System	05 Oct 2020 20:06:47
User entered 'No (N)'	System	05 Oct 2020 20:06:47

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bc37fd94-976b-4bb1-87f3-0319610d0c0d'	System	05 Oct 2020 20:06:47
User entered '05 Oct 2020 15:06'	System	05 Oct 2020 20:06:47

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:55'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 2'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T13:58:27', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '967694dd-8fc3-48fc-9706-737c96813d47'	System	06 Oct 2020 19:00:51
User entered 'Yes (Y)'	System	06 Oct 2020 19:00:51

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '967694dd-8fc3-48fc-9706-737c96813d47'	System	06 Oct 2020 19:00:51
User entered '95.8'	System	06 Oct 2020 19:00:51

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '967694dd-8fc3-48fc-9706-737c96813d47'	System	06 Oct 2020 19:00:51
User entered 'No (N)'	System	06 Oct 2020 19:00:51

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '967694dd-8fc3-48fe-9706-737c96813d47'	System	06 Oct 2020 19:00:51
User entered '06 Oct 2020 14:00'	System	06 Oct 2020 19:00:51

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 3'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:00:22', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ea342d29-d461-4a59-bb26-cd5f4de7db02'	System	07 Oct 2020 17:01:16
User entered 'Yes (Y)'	System	07 Oct 2020 17:01:16

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:00:30', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ea342d29-d461-4a59-bb26-cd5f4de7db02'	System	07 Oct 2020 17:01:16
User entered '96.1'	System	07 Oct 2020 17:01:16

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:00:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ea342d29-d461-4a59-bb26-cd5f4de7db02'	System	07 Oct 2020 17:01:16
User entered 'No (N)'	System	07 Oct 2020 17:01:16

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:00:50', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'ea342d29-d461-4a59-bb26-cd5f4de7db02'	System	07 Oct 2020 17:01:16
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 17:01:16

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 4'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:35', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '892caa7d-c714-430e-b5b6-8fd43a558ae9'	System	08 Oct 2020 17:01:11
User entered 'Yes (Y)'	System	08 Oct 2020 17:01:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '892caa7d-c714-430e-b5b6-8fd43a558ae9'	System	08 Oct 2020 17:01:11
User entered '96.2'	System	08 Oct 2020 17:01:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '892caa7d-c714-430e-b5b6-8fd43a558ae9'	System	08 Oct 2020 17:01:11
User entered 'No (N)'	System	08 Oct 2020 17:01:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:46', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '892caa7d-c714-430e-b5b6-8fd43a558ae9'	System	08 Oct 2020 17:01:11
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 17:01:11

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 5'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c99d38ae-dc2e-47bd-aa1c-049d801f8841'	System	09 Oct 2020 17:02:20
User entered 'Yes (Y)'	System	09 Oct 2020 17:02:20

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c99d38ae-dc2e-47bd-aa1c-049d801f8841'	System	09 Oct 2020 17:02:20
User entered '96.8'	System	09 Oct 2020 17:02:20

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:15', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c99d38ae-dc2e-47bd-aa1c-049d801f8841'	System	09 Oct 2020 17:02:20
User entered 'No (N)'	System	09 Oct 2020 17:02:20

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:17', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c99d38ae-dc2e-47bd-aa1c-049d801f8841'	System	09 Oct 2020 17:02:20
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 17:02:20

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 6'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:20', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'adadd69f-44df-4d09-b164-3541bd32c767'	System	10 Oct 2020 17:01:39
User entered 'Yes (Y)'	System	10 Oct 2020 17:01:39

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:25', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'adadd69f-44df-4d09-b164-3541bd32c767'	System	10 Oct 2020 17:01:39
User entered '97.2'	System	10 Oct 2020 17:01:39

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:28', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'adadd69f-44df-4d09-b164-3541bd32c767'	System	10 Oct 2020 17:01:39
User entered 'No (N)'	System	10 Oct 2020 17:01:39

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:32', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'adadd69f-44df-4d09-b164-3541bd32c767'	System	10 Oct 2020 17:01:39
User entered '10 Oct 2020 12:01'	System	10 Oct 2020 17:01:39

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 7'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:25', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '95ab61fd-d210-47e5-8cb2-3702fae5f7dd'	System	11 Oct 2020 17:02:44
User entered 'Yes (Y)'	System	11 Oct 2020 17:02:44

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:33', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '95ab61fd-d210-47e5-8cb2-3702fae5f7dd'	System	11 Oct 2020 17:02:44
User entered '97.3'	System	11 Oct 2020 17:02:44

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:35', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '95ab61fd-d210-47e5-8cb2-3702fae5f7dd'	System	11 Oct 2020 17:02:44
User entered 'No (N)'	System	11 Oct 2020 17:02:44

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '95ab61fd-d210-47e5-8cb2-3702fae5f7dd'	System	11 Oct 2020 17:02:44
User entered '11 Oct 2020 12:02'	System	11 Oct 2020 17:02:44

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '539dd29f-a0a0-433f-a53c-df43d4a57c3f'	System	05 Oct 2020 14:42:42
User entered 'None (1)'	System	05 Oct 2020 14:42:42

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:15', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '539dd29f-a0a0-433f-a53c-df43d4a57c3f'	System	05 Oct 2020 14:42:42
User entered 'No (N)'	System	05 Oct 2020 14:42:42

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:33', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '539dd29f-a0a0-433f-a53c-df43d4a57c3f'	System	05 Oct 2020 14:42:42
User entered 'No (N)'	System	05 Oct 2020 14:42:42

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '539dd29f-a0a0-433f-a53c-df43d4a57c3f'	System	05 Oct 2020 14:42:42
User entered 'None (1)'	System	05 Oct 2020 14:42:42

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '539dd29f-a0a0-433f-a53c-df43d4a57c3f'	System	05 Oct 2020 14:42:42
User entered '05 Oct 2020 09:42'	System	05 Oct 2020 14:42:42

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 09:30'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:46', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '2b926f93-6a45-44fc-a119-f189b315f138'	System	05 Oct 2020 20:07:05
User entered 'None (1)'	System	05 Oct 2020 20:07:05

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '2b926f93-6a45-44fc-a119-f189b315f138'	System	05 Oct 2020 20:07:05
User entered 'No (N)'	System	05 Oct 2020 20:07:05

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '2b926f93-6a45-44fc-a119-f189b315f138'	System	05 Oct 2020 20:07:05
User entered 'No (N)'	System	05 Oct 2020 20:07:05

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '2b926f93-6a45-44fc-a119-f189b315f138'	System	05 Oct 2020 20:07:05
User entered 'None (1)'	System	05 Oct 2020 20:07:05

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:06:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '2b926f93-6a45-44fc-a119-f189b315f138'	System	05 Oct 2020 20:07:05
User entered '05 Oct 2020 15:06'	System	05 Oct 2020 20:07:05

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:55'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 2'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c76975a4-e832-4084-b70f-ca0d10b48e4b'	System	06 Oct 2020 19:01:12
User entered 'None (1)'	System	06 Oct 2020 19:01:12

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:56', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c76975a4-e832-4084-b70f-ca0d10b48e4b'	System	06 Oct 2020 19:01:12
User entered 'No (N)'	System	06 Oct 2020 19:01:12

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:00:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c76975a4-e832-4084-b70f-ca0d10b48e4b'	System	06 Oct 2020 19:01:12
User entered 'No (N)'	System	06 Oct 2020 19:01:12

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c76975a4-e832-4084-b70f-ca0d10b48e4b'	System	06 Oct 2020 19:01:12
User entered 'None (1)'	System	06 Oct 2020 19:01:12

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:03', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c76975a4-e832-4084-b70f-ca0d10b48e4b'	System	06 Oct 2020 19:01:12
User entered '06 Oct 2020 14:01'	System	06 Oct 2020 19:01:12

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 3'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:00:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e0b5ee58-a63c-4e0a-8ac3-8faafd1ee6c'	System	07 Oct 2020 17:01:49
User entered 'None (1)'	System	07 Oct 2020 17:01:49

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:04', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e0b5ee58-a63c-4e0a-8ac3-8faafd1eee6c'	System	07 Oct 2020 17:01:49
User entered 'No (N)'	System	07 Oct 2020 17:01:49

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e0b5ee58-a63c-4e0a-8ac3-8faafd1eee6c'	System	07 Oct 2020 17:01:49
User entered 'No (N)'	System	07 Oct 2020 17:01:49

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:10', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e0b5ee58-a63c-4e0a-8ac3-8faafd1ee6c'	System	07 Oct 2020 17:01:49
User entered 'None (1)'	System	07 Oct 2020 17:01:49

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'e0b5ee58-a63c-4e0a-8ac3-8faafd1eee6c'	System	07 Oct 2020 17:01:49
User entered '07 Oct 2020 12:01'	System	07 Oct 2020 17:01:49

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 4'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3292cd57-6488-41fb-a613-3c40a860cd28'	System	08 Oct 2020 17:01:31
User entered 'None (1)'	System	08 Oct 2020 17:01:31

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:52', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3292cd57-6488-41fb-a613-3c40a860cd28'	System	08 Oct 2020 17:01:31
User entered 'No (N)'	System	08 Oct 2020 17:01:31

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3292cd57-6488-41fb-a613-3c40a860cd28'	System	08 Oct 2020 17:01:31
User entered 'No (N)'	System	08 Oct 2020 17:01:31

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:00:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3292cd57-6488-41fb-a613-3c40a860cd28'	System	08 Oct 2020 17:01:31
User entered 'None (1)'	System	08 Oct 2020 17:01:31

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3292cd57-6488-41fb-a613-3c40a860cd28'	System	08 Oct 2020 17:01:31
User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:01:31

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 5'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:20', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f8938ca-adcc-41b2-a44a-8e782f5d58fe'	System	09 Oct 2020 17:02:35
User entered 'None (1)'	System	09 Oct 2020 17:02:35

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:24', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f8938ca-adcc-41b2-a44a-8e782f5d58fe'	System	09 Oct 2020 17:02:35
User entered 'No (N)'	System	09 Oct 2020 17:02:35

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:27', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f8938ca-adcc-41b2-a44a-8e782f5d58fe'	System	09 Oct 2020 17:02:35
User entered 'No (N)'	System	09 Oct 2020 17:02:35

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:29', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f8938ca-adcc-41b2-a44a-8e782f5d58fe'	System	09 Oct 2020 17:02:35
User entered 'None (1)'	System	09 Oct 2020 17:02:35

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:32', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '3f8938ca-adcc-41b2-a44a-8e782f5d58fe'	System	09 Oct 2020 17:02:35
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 17:02:35

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 6'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0b0ea214-71f6-4f6b-b9a9-7444c01b51ec'	System	10 Oct 2020 17:01:53
User entered 'None (1)'	System	10 Oct 2020 17:01:53

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0b0ea214-71f6-4f6b-b9a9-7444c01b51ec'	System	10 Oct 2020 17:01:53
User entered 'No (N)'	System	10 Oct 2020 17:01:53

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0b0ea214-71f6-4f6b-b9a9-7444c01b51ec'	System	10 Oct 2020 17:01:53
User entered 'No (N)'	System	10 Oct 2020 17:01:53

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0b0ea214-71f6-4f6b-b9a9-7444c01b51ec'	System	10 Oct 2020 17:01:53
User entered 'None (1)'	System	10 Oct 2020 17:01:53

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0b0ea214-71f6-4f6b-b9a9-7444c01b51ec'	System	10 Oct 2020 17:01:53
User entered '10 Oct 2020 12:01'	System	10 Oct 2020 17:01:53

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 7'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f7db317e-1bc0-440d-b278-8b73536e876f'	System	11 Oct 2020 17:03:09
User entered 'None (1)'	System	11 Oct 2020 17:03:09

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f7db317e-1bc0-440d-b278-8b73536e876f'	System	11 Oct 2020 17:03:09
User entered 'No (N)'	System	11 Oct 2020 17:03:09

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f7db317e-1bc0-440d-b278-8b73536e876f'	System	11 Oct 2020 17:03:09
User entered 'No (N)'	System	11 Oct 2020 17:03:09

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:02:56', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f7db317e-1bc0-440d-b278-8b73536e876f'	System	11 Oct 2020 17:03:09
User entered 'None (1)'	System	11 Oct 2020 17:03:09

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'f7db317e-1bc0-440d-b278-8b73536e876f'	System	11 Oct 2020 17:03:09
User entered '11 Oct 2020 12:03'	System	11 Oct 2020 17:03:09

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:47', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:55', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'None (0)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:42:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered 'No (N)'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T09:43:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0e5fdb4-8cce-474f-a835-1ca70f1afa9c'	System	05 Oct 2020 14:43:11
User entered '05 Oct 2020 09:43'	System	05 Oct 2020 14:43:11

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 09:30'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:04', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:09', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:11', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'None (0)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered 'No (N)'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-05T15:07:16', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '988134fb-9ca9-4d8b-b70f-26ffb9769d2f'	System	05 Oct 2020 20:07:21
User entered '05 Oct 2020 15:07'	System	05 Oct 2020 20:07:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '05 Oct 2020 12:55'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 2'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:09', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'None (0)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:19', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered 'No (N)'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-06T14:01:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '41a2db56-3f35-4590-9ed5-42747759ee41'	System	06 Oct 2020 19:01:26
User entered '06 Oct 2020 14:01'	System	06 Oct 2020 19:01:26

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 3'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:20', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:22', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:24', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:26', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:28', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'None (0)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:37', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered 'No (N)'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-07T12:01:46', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '750d8802-e164-4556-b8a9-dbfbeac938e6'	System	07 Oct 2020 17:02:18
User entered '07 Oct 2020 12:01'	System	07 Oct 2020 17:02:18

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 4'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:09', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:11', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:15', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'None (0)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:19', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered 'No (N)'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-08T12:01:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'c001f6ac-ce7f-4f36-80ee-6efa4e096618'	System	08 Oct 2020 17:02:05
User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:02:05

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 5'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:35', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'None (0)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered 'No (N)'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-09T12:02:47', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '280db347-2793-4a33-8848-0f2c8d7c5099'	System	09 Oct 2020 17:02:50
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 17:02:50

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 6'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:01:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:01', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:04', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'None (0)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:11', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered 'No (N)'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-10T12:02:16', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '4821ac1a-2e8a-4a8b-bfad-7d37c16f26a3'	System	10 Oct 2020 17:02:21
User entered '10 Oct 2020 12:02'	System	10 Oct 2020 17:02:21

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	05 Oct 2020 14:23:13
User entered 'Day 7'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:07', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:10', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:14', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'None (0)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:17', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered 'No (N)'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-10-11T12:03:19', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '648c5f1f-5677-44c5-872b-5e339717842c'	System	11 Oct 2020 17:03:25
User entered '11 Oct 2020 12:03'	System	11 Oct 2020 17:03:25

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 14:23:13

US3572199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:19:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 14:23:13

US3572199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:04
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:09:15

US3572199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:04
User entered '13 Oct 2020'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:09:15

US3572199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:04
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:17:13
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:09:15

US3572199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:04
User entered 'voicemail for day 36 safety call 10:08am'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:09:15

US3572199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:07
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:17:19

US3572199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'l'	System	13 Oct 2020 15:17:19

US3572199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:57:34

US3572199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:15
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 18:57:34

US3572199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 18:57:34

US3572199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:15
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:57:34

US3572199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:57:41

US3572199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'l'	System	19 Oct 2020 18:57:41

US3572199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 17:26:21

US3572199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:33
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 16:08:32
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 17:26:21

US3572199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:33
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 16:08:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	26 Oct 2020 17:26:21

US3572199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 16:08:32
User entered 'left voicemail'	(b) (4), (b) (6)	26 Oct 2020 17:26:21

US3572199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:54:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 16:08:39

US3572199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'l'	System	27 Nov 2020 16:08:39

US3572199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:51:31

US3572199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:02:56
User entered '4 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:51:31

US3572199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:02:56
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Dec 2020 16:51:31

US3572199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'VISIT3'	System	08 Dec 2020 16:51:31

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '4 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '10:10'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '4 Nov 2020 10:10'	System	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '97.7' F	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered 'TEMPORAL'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '60'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'bpm'	System	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '18'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'breaths/min'	System	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '121'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:27
User entered '82'	(b) (4), (b) (6)	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'mmHg'	System	08 Dec 2020 16:53:15

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42

US3572199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42

US3572199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:53:30

US3572199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:48
User entered '4 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:53:30

US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 16:54:04

US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 3 Day 57 sample with Accession # 1F637955267. Per response if 10Nov2020 was not collected for this subject then please review the Accession # 1F637955267 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs' (Site from DM).	(b) (4) (u) (4), (b) (6)	03 Mar 2021 07:49:25
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 3 Day 57 sample with Accession # 1F637955267. Per response if 10Nov2020 was not collected for this subject then please review the Accession # 1F637955267 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs' answered with 'accession - 1F60GBK collection date 04Nov2020 US3572199 ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:47:12
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: PPD records an additional Visit 3 Day 57 sample with Accession # 1F637955267. Per response if 10Nov2020 was not collected for this subject then please review the Accession # 1F637955267 in Preclarus and confirm the correct subject ID and Visit label to which the subject belongs' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:23:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: As per the PPD there were two samples dated 04 NOV 2020 and 10 NOV 2020 collected for V3D57, in EDC 04 NOV 2020 recorded in the V3D57 in EDC and 10 NOV 2020 sample is missing, Please review and update the 10 NOV 2020 sample as it is still missing in EDC. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:22:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: As per the PPD there were two samples dated 04 NOV 2020 and 10 NOV 2020 collected for V3D57, in EDC 04 NOV 2020 recorded in the V3D57 in EDC and 10 NOV 2020 sample is missing, Please review and update the 10 NOV 2020 sample as it is still missing in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:14:49
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10NOV2020 for the Visit 3 Day 57 Visit, however, the Collection Date recorded here is 04NOV2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:14:49
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10NOV2020 for the Visit 3 Day 57 Visit, however, the Collection Date recorded here is 04NOV2020. Please confirm the correct Collection Date in the query response and update if appropriate.' answered with 'Immuno sample collected on V3D57 was collected on 04NOV2020. There was no sample collected on 10Nov2020 for this subject. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 03:56:08
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10NOV2020 for the Visit 3 Day 57 Visit, however, the Collection Date recorded here is 04NOV2020. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:41:16
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:03:57
User entered '4 Nov 2020'	(b) (4), (b) (6)	08 Dec 2020 16:54:04

US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:03:57
User entered '10:30'	(b) (4), (b) (6)	08 Dec 2020 16:54:04

US3572199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered '4 Nov 2020 10:30'	System	08 Dec 2020 16:54:04

US3572199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:16:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:04:00
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:41:54
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:54:17
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 19:48:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Nov 2020 16:09:49

US3572199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'l'	System	27 Nov 2020 16:09:49

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 64'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-04T11:06:22', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '14fef2fe-56e5-4660-bf8a-026c4ad9fdb6'	System	04 Nov 2020 17:08:35
User entered 'No (N)'	System	04 Nov 2020 17:08:35

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-04T11:06:33', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '14fef2fe-56e5-4660-bf8a-026c4ad9fdb6'	System	04 Nov 2020 17:08:35
User entered 'No (N)'	System	04 Nov 2020 17:08:35

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-04T11:07:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '14fef2fe-56e5-4660-bf8a-026c4ad9fdb6'	System	04 Nov 2020 17:08:35
User entered '04 Nov 2020 11:07:05'	System	04 Nov 2020 17:08:35

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 71'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-11T09:16:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b231c75a-5b2a-41e7-862a-7112cdea211c'	System	11 Nov 2020 15:16:38
User entered 'No (N)'	System	11 Nov 2020 15:16:38

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-11T09:16:21', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b231c75a-5b2a-41e7-862a-7112cdea211c'	System	11 Nov 2020 15:16:38
User entered 'No (N)'	System	11 Nov 2020 15:16:38

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-11T09:16:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b231c75a-5b2a-41e7-862a-7112cdea211c'	System	11 Nov 2020 15:16:38
User entered '11 Nov 2020 09:16:34'	System	11 Nov 2020 15:16:38

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered 'Day 78'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-18T00:01:57', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7162d72f-a4b6-4c35-82c2-88bb979ad86d'	System	18 Nov 2020 06:02:20
User entered 'No (N)'	System	18 Nov 2020 06:02:20

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-18T00:02:13', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7162d72f-a4b6-4c35-82c2-88bb979ad86d'	System	18 Nov 2020 06:02:20
User entered 'No (N)'	System	18 Nov 2020 06:02:20

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-18T00:02:17', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '7162d72f-a4b6-4c35-82c2-88bb979ad86d'	System	18 Nov 2020 06:02:20
User entered '18 Nov 2020 00:02:17'	System	18 Nov 2020 06:02:20

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 19:47:15

US3572199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:37:39
Data entry locked.	System	04 Sep 2020 19:47:15
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 19:47:15

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-11-23T16:15:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '01675f5d-ae47-4056-a2e9-7130eb793a45'	System	23 Nov 2020 22:15:47
User entered 'No (N)'	System	23 Nov 2020 22:15:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-11-23T16:15:41', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '01675f5d-ae47-4056-a2e9-7130eb793a45'	System	23 Nov 2020 22:15:47
User entered 'No (N)'	System	23 Nov 2020 22:15:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-23T16:15:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '01675f5d-ae47-4056-a2e9-7130eb793a45' User entered '23 Nov 2020 16:15:43'	System	23 Nov 2020 22:15:47
	System	23 Nov 2020 22:15:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-11-30T13:17:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd6d531a3-323f-475a-9d17-5306094e5af3'	System	30 Nov 2020 19:17:59
User entered 'No (N)'	System	30 Nov 2020 19:17:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-11-30T13:17:50', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd6d531a3-323f-475a-9d17-5306094e5af3'	System	30 Nov 2020 19:17:59
User entered 'No (N)'	System	30 Nov 2020 19:17:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-11-30T13:17:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd6d531a3-323f-475a-9d17-5306094e5af3'	System	30 Nov 2020 19:17:59
User entered '30 Nov 2020 13:17:53'	System	30 Nov 2020 19:17:59

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-06T00:01:52', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '33f80d61-fd58-4fdf-b6d9-26216f100cae'	System	06 Dec 2020 06:02:27
User entered 'No (N)'	System	06 Dec 2020 06:02:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-12-06T00:02:06', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '33f80d61-fd58-4fdf-b6d9-26216f100cae'	System	06 Dec 2020 06:02:27
User entered 'No (N)'	System	06 Dec 2020 06:02:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-06T00:02:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '33f80d61-fd58-4fdf-b6d9-26216f100cae'	System	06 Dec 2020 06:02:27
User entered '06 Dec 2020 00:02:08'	System	06 Dec 2020 06:02:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-13T00:08:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd90ffec5-5c8c-4195-8b60-ba8dbaba1fd1'	System	13 Dec 2020 06:08:57
User entered 'No (N)'	System	13 Dec 2020 06:08:57

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-12-13T00:08:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd90ffec5-5c8c-4195-8b60-ba8dbaba1fd1'	System	13 Dec 2020 06:08:57
User entered 'No (N)'	System	13 Dec 2020 06:08:57

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-13T00:08:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd90ffec5-5c8c-4195-8b60-ba8dbaba1fd1' User entered '13 Dec 2020 00:08:54'	System	13 Dec 2020 06:08:57
	System	13 Dec 2020 06:08:57

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-20T01:57:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'Yes (Y)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-12-20T01:57:35', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'Yes (Y)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2020-12-20T01:57:42', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-20T01:57:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'Yes (Y)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'l'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '0'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:39', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered '1'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2020-12-20T01:58:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-20T01:58:47', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'Yes (Y)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2020-12-20T01:58:50', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264'	System	20 Dec 2020 07:59:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-20T01:58:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '15a8389b-d261-4264-94a2-02afdea28264' User entered '20 Dec 2020 01:58:54'	System	20 Dec 2020 07:59:05
	System	20 Dec 2020 07:59:05

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-27T02:23:23', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'Yes (Y)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2020-12-27T02:23:31', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'Yes (Y)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2020-12-27T02:23:54', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-27T02:24:05', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'Yes (Y)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de' User entered '0'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:24:44', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered '1'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2020-12-27T02:24:51', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2020-12-27T02:24:59', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'Yes (Y)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Please 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 (115f6debd1bc09a0)', Time: '2020-12-27T02:25:04', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2020-12-27T02:25:08', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'dcebd3b0-0dc4-4545-b18c-ceac7416d3de'	System	27 Dec 2020 08:25:18
User entered '27 Dec 2020 02:25:08'	System	27 Dec 2020 08:25:18

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-01-03T00:14:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '001bcb9d-dd7a-4f11-ac7e-b62108277425'	System	03 Jan 2021 06:15:29
User entered 'No (N)'	System	03 Jan 2021 06:15:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-01-03T00:15:02', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '001bcb9d-dd7a-4f11-ac7e-b62108277425'	System	03 Jan 2021 06:15:29
User entered 'Yes (Y)'	System	03 Jan 2021 06:15:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Please 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 (115f6debd1bc09a0)', Time: '2021-01-03T00:15:12', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '001bcb9d-dd7a-4f11-ac7e-b62108277425'	System	03 Jan 2021 06:15:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 06:15:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-01-03T00:15:18', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '001bcb9d-dd7a-4f11-ac7e-b62108277425'	System	03 Jan 2021 06:15:29
User entered '03 Jan 2021 00:15:18'	System	03 Jan 2021 06:15:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-01-24T06:54:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '9f01ba71-9bec-4938-a283-b59a15626cea'	System	24 Jan 2021 12:54:49
User entered 'No (N)'	System	24 Jan 2021 12:54:49

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-01-24T06:54:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '9f01ba71-9bec-4938-a283-b59a15626cea'	System	24 Jan 2021 12:54:49
User entered 'No (N)'	System	24 Jan 2021 12:54:49

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-01-24T06:54:48', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '9f01ba71-9bec-4938-a283-b59a15626cea' User entered '24 Jan 2021 06:54:48'	System	24 Jan 2021 12:54:49

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-01-31T05:20:45', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '172e4dd4-e297-44c6-bfb7-7961cd7c5512'	System	31 Jan 2021 11:21:40
User entered 'No (N)'	System	31 Jan 2021 11:21:40

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-01-31T05:20:58', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '172e4dd4-e297-44c6-bfb7-7961cd7c5512'	System	31 Jan 2021 11:21:40
User entered 'No (N)'	System	31 Jan 2021 11:21:40

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-01-31T05:21:37', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '172e4dd4-e297-44c6-bfb7-7961cd7c5512' User entered '31 Jan 2021 05:21:37'	System	31 Jan 2021 11:21:40
	System	31 Jan 2021 11:21:40

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-02-07T03:15:49', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b8fc4162-d9ed-4f61-a1f9-b965cba58f1c'	System	07 Feb 2021 09:16:03
User entered 'No (N)'	System	07 Feb 2021 09:16:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-02-07T03:15:53', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b8fc4162-d9ed-4f61-a1f9-b965cba58f1c'	System	07 Feb 2021 09:16:03
User entered 'No (N)'	System	07 Feb 2021 09:16:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-02-07T03:15:58', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b8fc4162-d9ed-4f61-a1f9-b965cba58f1c' User entered '07 Feb 2021 03:15:58'	System	07 Feb 2021 09:16:03
	System	07 Feb 2021 09:16:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-02-14T18:53:26', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0436f801-cc34-4d4e-a327-9a5bcb1e60b9'	System	15 Feb 2021 00:53:47
User entered 'No (N)'	System	15 Feb 2021 00:53:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-02-14T18:53:40', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0436f801-cc34-4d4e-a327-9a5bcb1e60b9'	System	15 Feb 2021 00:53:47
User entered 'No (N)'	System	15 Feb 2021 00:53:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-02-14T18:53:43', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0436f801-cc34-4d4e-a327-9a5bcb1e60b9' User entered '14 Feb 2021 18:53:43'	System	15 Feb 2021 00:53:47

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-02-22T13:56:34', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'a9e06f41-0b5d-48ca-91cd-93fe65f2f619'	System	22 Feb 2021 19:56:42
User entered 'No (N)'	System	22 Feb 2021 19:56:42

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-02-22T13:56:36', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'a9e06f41-0b5d-48ca-91cd-93fe65f2f619'	System	22 Feb 2021 19:56:42
User entered 'No (N)'	System	22 Feb 2021 19:56:42

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-02-22T13:56:38', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'a9e06f41-0b5d-48ca-91cd-93fe65f2f619'	System	22 Feb 2021 19:56:42
User entered '22 Feb 2021 13:56:38'	System	22 Feb 2021 19:56:42

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-03-01T09:15:17-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '68549d62-e9e5-4391-841c-e59e4daaf0d'	System	01 Mar 2021 15:15:27
User entered 'No (N)'	System	01 Mar 2021 15:15:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-03-01T09:15:22-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '68549d62-e9e5-4391-841c-e59e4daaf0d'	System	01 Mar 2021 15:15:27
User entered 'No (N)'	System	01 Mar 2021 15:15:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-01T09:15:24-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '68549d62-e9e5-4391-841c-e59e4daaf0d'	System	01 Mar 2021 15:15:27
User entered '01 Mar 2021 09:15:24'	System	01 Mar 2021 15:15:27

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-03-07T00:04:39-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '014831e8-acbd-4e3f-a091-8fc512233a14'	System	07 Mar 2021 06:04:48
User entered 'No (N)'	System	07 Mar 2021 06:04:48

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-03-07T00:04:41-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '014831e8-acbd-4e3f-a091-8fc512233a14'	System	07 Mar 2021 06:04:48
User entered 'No (N)'	System	07 Mar 2021 06:04:48

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-07T00:04:44-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '014831e8-acbd-4e3f-a091-8fc512233a14'	System	07 Mar 2021 06:04:48
User entered '07 Mar 2021 00:04:44'	System	07 Mar 2021 06:04:48

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-03-14T00:02:54-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bd23c197-e3e2-4dd7-abc1-d518575b5505'	System	14 Mar 2021 06:03:09
User entered 'No (N)'	System	14 Mar 2021 06:03:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-03-14T00:02:57-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bd23c197-e3e2-4dd7-abc1-d518575b5505'	System	14 Mar 2021 06:03:09
User entered 'No (N)'	System	14 Mar 2021 06:03:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-14T00:03:05-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'bd23c197-e3e2-4dd7-abc1-d518575b5505'	System	14 Mar 2021 06:03:09
User entered '14 Mar 2021 00:03:05'	System	14 Mar 2021 06:03:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-03-21T00:01:17-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd9bc09ce-27a4-470f-b64a-a6d07e61f6f7'	System	21 Mar 2021 05:01:29
User entered 'No (N)'	System	21 Mar 2021 05:01:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-03-21T00:01:22-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd9bc09ce-27a4-470f-b64a-a6d07e61f6f7'	System	21 Mar 2021 05:01:29
User entered 'No (N)'	System	21 Mar 2021 05:01:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-21T00:01:24-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'd9bc09ce-27a4-470f-b64a-a6d07e61f6f7'	System	21 Mar 2021 05:01:29
User entered '21 Mar 2021 00:01:24'	System	21 Mar 2021 05:01:29

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-03-30T10:54:15-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '37ea2f7d-8fd9-493b-9ae4-7ed97f57a82f' User entered 'No (N)'	System	30 Mar 2021 15:54:25

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-03-30T10:54:18-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '37ea2f7d-8fd9-493b-9ae4-7ed97f57a82f' User entered 'No (N)'	System	30 Mar 2021 15:54:25

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-30T10:54:20-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '37ea2f7d-8fd9-493b-9ae4-7ed97f57a82f' User entered '30 Mar 2021 10:54:20'	System	30 Mar 2021 15:54:25
	System	30 Mar 2021 15:54:25

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-04-04T00:34:58-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0a3930e7-490b-4389-b871-58e46eaf7ec' User entered 'No (N)'	System	04 Apr 2021 05:35:09
	System	04 Apr 2021 05:35:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-04-04T00:35:00-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0a3930e7-490b-4389-b871-58e46eaf7ec' User entered 'No (N)'	System	04 Apr 2021 05:35:09
	System	04 Apr 2021 05:35:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-04-04T00:35:03-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '0a3930e7-490b-4389-b871-58e46eae7ec'	System	04 Apr 2021 05:35:09
User entered '04 Apr 2021 00:35:03'	System	04 Apr 2021 05:35:09

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-04-11T00:34:19-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '00fc487b-b9e1-458a-91ba-7513d91eb7f9'	System	11 Apr 2021 05:34:31
User entered 'No (N)'	System	11 Apr 2021 05:34:31

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-04-11T00:34:21-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '00fc487b-b9e1-458a-91ba-7513d91eb7f9'	System	11 Apr 2021 05:34:31
User entered 'No (N)'	System	11 Apr 2021 05:34:31

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-04-11T00:34:25-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '00fc487b-b9e1-458a-91ba-7513d91eb7f9'	System	11 Apr 2021 05:34:31
User entered '11 Apr 2021 00:34:25'	System	11 Apr 2021 05:34:31

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-04-18T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1d7065b8-529f-4575-81b6-c708b9ed9230'	System	18 Apr 2021 05:01:35
User entered 'No (N)'	System	18 Apr 2021 05:01:35

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-04-18T00:01:26-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1d7065b8-529f-4575-81b6-c708b9ed9230'	System	18 Apr 2021 05:01:35
User entered 'No (N)'	System	18 Apr 2021 05:01:35

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-04-18T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '1d7065b8-529f-4575-81b6-c708b9ed9230'	System	18 Apr 2021 05:01:35
User entered '18 Apr 2021 00:01:28'	System	18 Apr 2021 05:01:35

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-04-25T00:02:01-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b15d3f93-35f4-4434-9ecb-3ad8eb345397'	System	25 Apr 2021 05:02:16
User entered 'No (N)'	System	25 Apr 2021 05:02:16

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-04-25T00:02:10-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b15d3f93-35f4-4434-9ecb-3ad8eb345397'	System	25 Apr 2021 05:02:16
User entered 'No (N)'	System	25 Apr 2021 05:02:16

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-04-25T00:02:12-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: 'b15d3f93-35f4-4434-9ecb-3ad8eb345397'	System	25 Apr 2021 05:02:16
User entered '25 Apr 2021 00:02:12'	System	25 Apr 2021 05:02:16

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[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 (115f6debd1bc09a0)', Time: '2021-05-03T08:57:53-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '54d65f96-240b-4904-8e7c-4f7558b1a905'	System	03 May 2021 13:58:03
User entered 'No (N)'	System	03 May 2021 13:58:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Have you been exposed to someone with 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 (115f6debd1bc09a0)', Time: '2021-05-03T08:57:55-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '54d65f96-240b-4904-8e7c-4f7558b1a905'	System	03 May 2021 13:58:03
User entered 'No (N)'	System	03 May 2021 13:58:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-05-03T08:57:57-05:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '54d65f96-240b-4904-8e7c-4f7558b1a905'	System	03 May 2021 13:58:03
User entered '03 May 2021 08:57:57'	System	03 May 2021 13:58:03

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:13:50

US3572199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:50
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:13:50

US3572199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:19:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:18:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-01T09:15:02-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '79e77abe-78dc-4d9c-af8f-cfc8d0870e10'	System	01 Mar 2021 15:15:08
User entered 'No (N)'	System	01 Mar 2021 15:15:08

US3572199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:19:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:18:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (115f6debd1bc09a0)', Time: '2021-03-01T09:15:05-06:00', User OID: 'PatientReportedOutcome (US3572199)', ODM File OID: '79e77abe-78dc-4d9c-af8f-cfc8d0870e10'	System	01 Mar 2021 15:15:08
User entered '01 Mar 2021 09:15:05'	System	01 Mar 2021 15:15:08

US3572199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:43
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:27:39

US3572199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:43
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:52
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:27:39

US3572199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:43
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:27:39

US3572199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:43
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:52
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:27:39

US3572199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:02

US3572199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 17:22:42
User entered 'l'	System	08 Jan 2021 20:02:02

US3572199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:57
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:14

US3572199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:57
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:14

US3572199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:57
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:14

US3572199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:41:57
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:14

US3572199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:01
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:02:18

US3572199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User entered 'l'	System	08 Jan 2021 20:02:18

US3572199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:44:02
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:10:03
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'data for this sample/visit now entered in EDC' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:42:57
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:40:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 16:08:36

US3572199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:44:02
User entered '3 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 16:08:36

US3572199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:44:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Feb 2021 16:08:36

US3572199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:44:02
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 16:08:36

US3572199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:44:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 16:08:41

US3572199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User entered 'l'	System	03 Feb 2021 16:08:41

US3572199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Mar 2021 15:18:00

US3572199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '1 Mar 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Mar 2021 15:18:00

US3572199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Mar 2021 15:18:00

US3572199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Mar 2021 15:18:00

US3572199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	01 Mar 2021 15:18:08

US3572199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:12:54
User entered 'l'	System	01 Mar 2021 15:18:08

US3572199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:39:41

US3572199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:39:41

US3572199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:39:41

US3572199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 17:39:41

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10:50'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:50'	System	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '66'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '117'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '76'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:40:17

US3572199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:22

US3572199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:40:22

US3572199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:18

US3572199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:18

US3572199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10:50'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:18

US3572199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:50'	System	30 Mar 2021 17:42:18

US3572199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:42:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:21

US3572199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Mar 2021 17:42:21

US3572199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 15:01:33
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Apr 2021 16:46:23

US3572199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 15:01:33
User entered '3 May 2021' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	03 May 2021 14:05:13
User entered '30 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:46:23

US3572199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 15:01:33
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) (u) (4), (b) (6)	03 May 2021 14:05:13
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	30 Apr 2021 16:46:23

US3572199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 15:01:33
User entered empty; reason for change New Information	(b) (4) (u) (4), (b) (6)	03 May 2021 14:05:13
User entered 'Voicemail left.'	(b) (4), (b) (6)	30 Apr 2021 16:46:23

US3572199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 May 2021 15:01:33
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	03 May 2021 14:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 03:43:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 03:43:21

US3572199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 14:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	15 Apr 2021 03:43:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Apr 2021 03:43:21

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:31:16
User entered '19 Dec 2020'	(b) (4), (b) (6)	21 Apr 2021 21:16:56

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:31:16
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 21:17:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 21:17:22
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:17:22
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 21:16:56
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:16:56

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered '19 Dec 2020 12:00'	System	21 Apr 2021 21:17:22
User entered empty.	System	21 Apr 2021 21:16:56

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:31:16
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 21:17:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 21:17:22
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:17:22
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 21:16:56
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:16:56

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:31:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:17:40
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 21:16:56

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
User entered 'Day 1 (Day 1)'	(b) (4) (u) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered '19 Dec 2020'	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:07
User entered 'l'	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:07
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:04

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:18
User entered '19 Dec 2020'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[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 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[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 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (u) (4), (b) (6)	23 Apr 2021 10:20:02
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 00:32:18
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated ' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 21:19:05
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	21 Apr 2021 21:18:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:18
User entered '19 Dec 2020'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:18
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[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 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:18
User entered 'Laredo Medical Center Laboratory'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered 'I'	System	21 Apr 2021 21:18:48

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:46
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:32:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:46
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 21:20:19

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[Start Date](#)

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[Heart Rate](#)

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 19 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 00:32:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 21:20:19

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:10:24

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '13:10'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:10:24

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered '29 Dec 2020 13:10'	System	05 Jan 2021 21:10:24

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:10:24

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:10:24

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:18:54

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

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Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:19:34

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:20:18

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:27

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:21:45

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:02

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 7 (Day 7)'	(b) (4) (u) (4), (b) (6)	05 Jan 2021 21:22:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:22:16

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered empty.	System	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:19:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:23:10

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:24:05

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[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 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:24:05

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:19:26

[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 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:34:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 03:57:41
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:32
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed and updated' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 21:03:41
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	14 Apr 2021 20:51:54
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) System	16 Feb 2021 19:21:09

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Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered by data change (Site from System).	System	16 Feb 2021 19:21:09
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 19:21:09
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	05 Jan 2021 21:24:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 21:24:05

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Generated On: 10 Jun 2021 08:19:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
User closed query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab (dated:19-Dec-2020) is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 29-Dec-2020 as per Preclarus report, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Apr 2021 13:18:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 00:34:37
Query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab (dated:19-Dec-2020) is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 29-Dec-2020 as per Preclarus report, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you. ' answered with 'INFORMATION HAS BEEN ADDED AND UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:19:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:19:04

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Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab (dated:19-Dec-2020) is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 29-Dec-2020 as per Preclarus report, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 06:28:10
DataPoint Verified.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 03:45:32
User entered '19 Dec 2020' reason for change: Data Entry Error User signature succeeded.	(b) (4), (b) (6)	14 Apr 2021 20:59:04
User closed query 'Per GCL Lab Reconciliation: Response to previous query "accession 1F60GBK tracking 939474285403". accession number and tracking details are not matching with GCL. please provide correct details of both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).	Milton Haber (b) (4)	03 Apr 2021 04:45:16
Query 'Per GCL Lab Reconciliation: Response to previous query "accession 1F60GBK tracking 939474285403". accession number and tracking details are not matching with GCL. please provide correct details of both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' answered with 'DCF was submitted to PPD ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:31:48
	(b) (4), (b) (6)	16 Mar 2021 15:22:38

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[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Response to previous query "accession 1F60GBK tracking 939474285403". accession number and tracking details are not matching with GCL. please provide correct details of both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:46:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:46:59
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'accession 1F60GBK tracking 939474285403 ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:47:50
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample swab sample for 29-DEC-2020 is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession, tracking number, shipped date, else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:43:18
User entered '29 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 21:24:05

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:24:05

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:45:32
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:24:05

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[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 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:34:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:32
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	05 Jan 2021 21:24:05

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:34:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:32
User entered 'Laredo Medical Center LABORATORY' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 21:06:46
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User entered 'Doctors Hospital of Laredo Laboratory' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Jan 2021 21:24:05

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Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:38
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 00:34:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:19:04
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:32
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 20:51:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Jan 2021 21:24:05

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User entered '0'	System	21 Apr 2021 21:19:04
User entered '1'	System	14 Apr 2021 20:51:54
User entered '0'	System	16 Feb 2021 19:21:09
User entered '1'	System	05 Jan 2021 21:24:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 21:07:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 21:07:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 21:07:16
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 21:06:30
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Generated On: 10 Jun 2021 08:19:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Folder: Covid-19 Assessment 29 Dec 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

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Generated On: 10 Jun 2021 08:19:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

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[Start Date](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
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US3572199

Folder: Covid-19 Assessment 29 Dec 2020

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Generated On: 10 Jun 2021 08:19:26

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
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User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
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US3572199

Folder: Covid-19 Assessment 29 Dec 2020

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
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Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
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Folder: Covid-19 Assessment 29 Dec 2020

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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US3572199

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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[Date of Assessment](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 03:45:42
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[Date of Assessment](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:19:26

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:06:30

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:05
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:45:42
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 21:06:30

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '1 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '7 Jan 2021'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:57
Signature has been broken.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:43:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:43:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:00:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'not collected' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:42:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:51:01
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '19 Jan 2021'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:19:26

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:19:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:14
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:05:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per GCL Lab Recon: SALIVA: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC however the same is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 07:46:20
' (Site from DM). Query 'Per GCL Lab Recon: SALIVA: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC however the same is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4), (b) (6)	09 Mar 2021 16:19:34
' answered with 'DCF has been submitted to PPD for visit change. Visit Day 28 ' (Site from DM). User opened query 'Per GCL Lab Recon: SALIVA: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC however the same is reported under UNSCHEDULED visit in PPD Central Lab. Please confirm the correct Visit Label in the response and update in Preclarus PPD portal as appropriate so that there is matching of data between EDC & PPD GCL records. Thank you.	(b) (4), (b) (6)	04 Mar 2021 22:06:43
' (Site from DM). User entered '3 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 23:11:04

US3572199

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:16
User entered '29 Dec 2020'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[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 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:16
User entered 'Clinic (Clinic)'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered 'SICKD1'	System	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '29 Dec 2020'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '15:27'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered '29 Dec 2020 15:27'	System	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '63' in	(b) (4)	
	Maria Candelario (b) (4)	05 Jan 2021 18:03:00
DataPoint set to visible.	(b) (4)	
	System	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '120' lb	(b) (4) Maria Candelario (b) (4)	05 Jan 2021 18:03:00
DataPoint set to visible.	(b) (4) System	05 Jan 2021 17:52:34

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '98.1' F reason for change: Data Entry Error	System	05 Jan 2021 21:03:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 21:03:11
User entered '98.1' (non-conformant).	System	05 Jan 2021 18:03:00
	Maria Candelario (b) (4)	05 Jan 2021 18:03:00
	(b) (4)	

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User entered 'Forehead'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User entered '83'	Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered 'bpm'	System	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered 'breaths/min'	System	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '110'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered 'mmHg'	System	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '83'	(b) (4) Maria Candelario (b) (4) (b) (4)	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
User entered 'mmHg'	System	05 Jan 2021 18:03:00

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32

US3572199

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32

US3572199

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:05:06

US3572199

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:05:06

US3572199

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:19:26

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 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness 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 or provide clarification. Thank you.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 06:26:08
' (Site from DM).		
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness 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 or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:26:06
Query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness 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 or provide clarification. Thank you.	(b) (4), (b) (6)	23 Feb 2021 19:37:07
' answered with 'saliva sample already in EDC' (Site from DM).		
Query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness 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 or provide clarification. Thank you.' answered with 'confirmed saliva sample already in EDC ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 19:36:35

US3572199

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:19:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness 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 or provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:34:06
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness 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 or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:40:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 21:05:41

US3572199

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per GCL Lab Recon:Saliva: Sample dated 01 JAN 2021 is reported under Illness 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 or provide clarification. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 06:26:01
Query 'Per GCL Lab Recon:Saliva: Sample dated 01 JAN 2021 is reported under Illness 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 or provide clarification. Thank you. ' answered with 'saliva sample already in EDC ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 19:37:16
User opened query 'Per GCL Lab Recon:Saliva: Sample dated 01 JAN 2021 is reported under Illness 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 or provide clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:31:16
User entered '29 Dec 2020'	(b) (4), (b) (6)	05 Jan 2021 21:05:41

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '3 Feb 2021'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:38
User entered 'SICKD28'	System	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '17:40'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
User entered '3 Feb 2021 17:40'	System	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16
DataPoint set to visible.	System	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16
DataPoint set to visible.	System	09 Feb 2021 23:07:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '98.1' F	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'INFRARED/FOREHEAD'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '78'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
User entered 'bpm'	System	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '18'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
User entered 'breaths/min'	System	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '125'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
User entered 'mmHg'	System	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '85'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46
User entered 'mmHg'	System	09 Feb 2021 23:08:16

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:46

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:30

US3572199

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:57:52
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 23:08:30

US3572199

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:19:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 23:08:37

US3572199

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:19:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:58:01
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:46:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 07:01:15
' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.	(b) (4), (b) (6)	09 Mar 2021 17:09:09
' answered with 'dcf has been submitted to PPD for visit change. ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 FEB 2021 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.	(b) (4), (b) (6)	08 Mar 2021 09:17:46
' (Site from DM). User entered '3 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 23:08:37

US3572199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:23

US3572199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:23

US3572199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:23

US3572199

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 01:43:23

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:44:36

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:44:36

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'I'	System	23 Feb 2021 01:43:53

US3572199

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'I'	System	23 Feb 2021 01:43:53

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered empty.	System	23 Feb 2021 01:45:57
DataPoint set to visible.	System	23 Feb 2021 01:43:53

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered empty.	System	23 Feb 2021 01:45:57
DataPoint set to visible.	System	23 Feb 2021 01:43:53

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '17:40'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered '03 Feb 2021 17:40'	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:46:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:46:36
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:46:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:46:36
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'bpm'	System	23 Feb 2021 01:46:36
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:46:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:46:36
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'breaths/min'	System	23 Feb 2021 01:46:36
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 01:46:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 01:46:36
User entered '125' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'mmHg'	System	23 Feb 2021 01:46:36
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 01:46:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 01:46:36
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:46:36
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'mmHg'	System	23 Feb 2021 01:46:36
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered empty.	System	23 Feb 2021 01:45:57
DataPoint set to visible.	System	23 Feb 2021 01:43:53

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '19:17'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered '03 Feb 2021 19:17'	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:47:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:47:30
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 01:47:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 01:47:30
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'bpm'	System	23 Feb 2021 01:47:30
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:47:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:47:30
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'breaths/min'	System	23 Feb 2021 01:47:30
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 01:47:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 01:47:30
User entered '122' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'mmHg'	System	23 Feb 2021 01:47:30
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:15
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:45:31
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:47:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 01:47:30
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 01:47:30
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 01:45:57
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 01:45:57

US3572199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'mmHg'	System	23 Feb 2021 01:47:30
User entered empty.	System	23 Feb 2021 01:45:57

US3572199

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:05

US3572199

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:45:05

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (+), (b) (6)	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'mRNA-1273'	System	23 Feb 2021 01:47:58
DataPoint set to visible.	System	23 Feb 2021 01:43:53

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18:47'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:47:58

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered '03 Feb 2021 18:47'	System	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:26
User entered 'ONCE'	System	23 Feb 2021 01:47:58

US3572199

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

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 01:47:58

US3572199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:44:19

US3572199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:17:43
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'AWB - 939474285778 accession 1F60GBK' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:17:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:04:30
User entered '02 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 01:44:19

US3572199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '14:47'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:44:19

US3572199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered '02 Feb 2021 14:47'	System	23 Feb 2021 01:44:19

US3572199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:44:40

US3572199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:44:40

US3572199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:36
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '14:38'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:44:40

US3572199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered '02 Feb 2021 14:38'	System	23 Feb 2021 01:44:40

US3572199

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

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:48:04

US3572199

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

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:20:49
User entered 'I'	System	23 Feb 2021 01:48:04

US3572199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:56
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:48:38

US3572199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:56
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:48:38

US3572199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:56
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 01:48:38

US3572199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:47:56
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (+), (b) (6)	23 Feb 2021 01:48:38

US3572199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:02
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 01:48:44

US3572199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User entered 'l'	System	23 Feb 2021 01:48:44

US3572199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User entered 'I'	System	23 Feb 2021 01:48:44
DataPoint set to visible.	System	23 Feb 2021 01:48:44

US3572199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:35:33

US3572199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10 Mar 2021'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:35:33

US3572199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:35:33

US3572199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'OLD29'	System	10 Mar 2021 23:35:33

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '15:05'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered '10 Mar 2021 15:05'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '69'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'bpm'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'breaths/min'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '120'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'mmHg'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '76'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'mmHg'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '15:55'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered '10 Mar 2021 15:55'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'TRMPORAL'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '72'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'bpm'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'breaths/min'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '117'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'mmHg'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '85'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'mmHg'	System	10 Mar 2021 23:38:20

US3572199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:25

US3572199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:25

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'mRNA-1273'	System	10 Mar 2021 23:38:41
DataPoint set to visible.	System	23 Feb 2021 01:48:44

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '15:25'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered '10 Mar 2021 15:25'	System	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:37
User entered 'ONCE'	System	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 23:38:41

US3572199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Mar 2021 23:38:45

US3572199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:32:18
User entered 'l'	System	10 Mar 2021 23:38:45

US3572199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:51:22

US3572199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:51:22

US3572199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:51:22

US3572199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:51:22

US3572199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:48:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	17 Mar 2021 13:51:29

US3572199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:31
User entered 'l'	System	17 Mar 2021 13:51:29

US3572199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:35:36

US3572199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (u) (4), (b) (6)	31 Mar 2021 04:17:39
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'SUBJECT HAD WORK SCHEDULE CONFLICT' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 17:35:50
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 17:35:36
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 17:35:36

US3572199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[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 04:45:31
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:35:36

US3572199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 17:35:36

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '30 Mar 2021'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10:48'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:48'	System	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '98.1' F	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '66'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '18'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '117'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '76'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 17:36:29

US3572199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:35

US3572199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:36:35

US3572199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:38:45

US3572199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '30 Mar 2021'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:38:45

US3572199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '10:50'	(b) (4) (u) (4), (b) (6)	30 Mar 2021 17:38:45

US3572199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:50'	System	30 Mar 2021 17:38:45

US3572199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:19:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:59:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per CDM RQ: Response to any adverse events is NO, however adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 03:24:42
Query 'Per CDM RQ: Response to any adverse events is NO, however adverse events are recorded on corresponding page. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:14:48
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	08 Feb 2021 07:14:37
User opened query 'Per CDM RQ: Response to any adverse events is NO, however adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 03:05:52
User closed query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 03:05:52
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Feb 2021 16:08:53
Query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 17:40:24
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:40:18
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:00:30
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Jan 2021 20:02:40

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:19:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Jasmine Ali (b) (4)	13 Oct 2020 15:17:26
User entered 'No (N)'	Jessica McDowell (b) (4)	11 Sep 2020 17:45:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Eye injuries NEC, PT: Superficial injury of eye, LLT: Scratch eye - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 16:21:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Oct 2020 16:21:22
Data point term sent to Coder	System	13 Oct 2020 15:18:23
User entered 'scratch to right eye'	Jasmine Ali (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. 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)	26 Nov 2020 04:57:41
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:47:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 01:47:50
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. 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)	02 Nov 2020 11:03:09
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '2 Oct 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
User entered empty.	System	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '12 Oct 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
User entered empty.	System	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Nov 2020 01:47:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 01:47:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 01:47:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 15:18:11
User entered empty.	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Nov 2020 01:47:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 01:47:50
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 01:47:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 15:18:11
User entered empty.	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	25 Nov 2020 01:47:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 01:47:50
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 01:47:50
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 15:18:11
User entered empty.	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'l'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
User entered '0'	System	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50
User entered 'I'	System	13 Oct 2020 15:18:11

US3572199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:25
User entered 'USA-US091-2020-mRNA-1273-P301000008'	System	31 Dec 2020 18:36:00
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 18:36:00
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 16:08:04

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis aggravated - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:30:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:30:31
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Per DM CLR RQ: Response noted. However please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:01:43
Query 'Per DM CLR RQ: Response noted. However please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate.' answered with 'Data updated as per query' (Site from DM).	Maria Candelario (b) (4)	19 Mar 2021 16:05:01
Data point term sent to Coder	System	19 Mar 2021 16:02:29
Coding entries removed.	Maria Candelario (b) (4)	19 Mar 2021 16:01:32
User entered 'Worsening of COLITIS' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR RQ: Response noted. However please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate.' (Site from DM).	Maria Candelario (b) (4)	19 Mar 2021 16:01:32
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:47:51
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Updated, subject had acute hemorrhagic colitis, has resolved since 11Jan2021' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:24:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Ulcerative Colitis. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:04:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Enterocolitis haemorrhagic, LLT: Hemorrhagic colitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 19:06:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 19:06:19
Data point term sent to Coder	System	30 Dec 2020 17:12:25
User entered 'Acute Hemorrhagic Colitis'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '12 Dec 2020'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	02 Feb 2021 05:40:21
User entered 'No (N)' reason for change: Data Entry Error	System	02 Feb 2021 05:40:21
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Milton Haber (b) (4)	02 Feb 2021 05:40:21
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 05:39:54
	Maria Candelario (b) (4)	30 Dec 2020 17:11:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:28:38
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Feb 2021 05:41:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Feb 2021 05:41:31
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'End date provided ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:40:41
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Feb 2021 05:39:54
User entered '11 Jan 2021' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:39:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:54:48
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:54:27
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:35:18
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: Since the subject was hospitalized for the event of acute hemorrhagic colitis, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain. ' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 19:00:24
User opened query 'PV Query: Since the subject was hospitalized for the event of acute hemorrhagic colitis, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:16:20
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 05:39:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 05:39:54
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:39:54
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:11:50
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	04 Jan 2021 06:59:26
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Dec 2020 17:11:50
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	04 Jan 2021 06:59:26
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	04 Jan 2021 06:59:26
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 06:59:26
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Dec 2020 17:11:50
User entered '0'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '19 Dec 2020'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:23:29
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Fax was sent as requested' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	03 Feb 2021 17:46:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:48:03
User entered '24 Dec 2020'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'provided ' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 14:28:43
User closed query 'Data is required. Please complete.' (Site from System).	Milton Haber (b) (4)	02 Feb 2021 05:42:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	02 Feb 2021 05:39:54
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	System	02 Feb 2021 05:39:54
User opened query 'Data is required. Please complete.' (Site from System).	Milton Haber (b) (4)	02 Feb 2021 05:39:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Jan 2021 15:09:26
	System	30 Dec 2020 17:11:50
	Maria Candelario (b) (4)	30 Dec 2020 17:11:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:29:09
Query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible' answered with 'provided ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:42:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 05:39:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 05:39:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:39:54
User opened query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:43:28
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:11:50
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User closed query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:27:03
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' answered with 'Data updated' (Site from Safety).	Maria Candelario (b) (4)	19 Mar 2021 16:05:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 16:05:27
User opened query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:11:04
User closed query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:11:17
Query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' answered with 'None' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:32:31
User opened query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:14:37
User closed query 'PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 14:29:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis.' answered with 'provided ' (Site from Safety).	Milton Haber (b) (4)	02 Feb 2021 05:42:13
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 Feb 2021 05:41:31
User entered 'None (NONE)' reason for change: Data Entry Error	System	02 Feb 2021 05:41:31
User opened query 'PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis.' (Site from Safety).	Milton Haber (b) (4)	02 Feb 2021 05:41:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 14:34:47
	System	30 Dec 2020 17:11:50
	Maria Candelario (b) (4)	30 Dec 2020 17:11:50
	(b) (4)	

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	18 Feb 2021 05:33:43
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Caitlin roll (b) (4)	16 Feb 2021 18:38:10
User entered '0' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 18:38:04
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(u) (4), (b) (6)	08 Feb 2021 05:17:17
User entered '1'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '1' reason for change: Data Entry Error	(b) (4) Caitlin roll (b) (4)	16 Feb 2021 18:38:04
User entered '0'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:29:17
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'resolution occurred ' (Site from Safety).	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:42:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Milton Haber (b) (4) (b) (4)	02 Feb 2021 05:41:31
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:35:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4) Maria Candelario (b) (4)	30 Dec 2020 17:11:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:43:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:43:31
Query 'PV Query: Please provide information on the history of ulcerative colitis: the diagnostic criteria of ulcerative colitis; frequency of flare and remission; treatment history.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:40:52
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:40:10
User opened query 'PV Query: Please provide information on the history of ulcerative colitis: the diagnostic criteria of ulcerative colitis; frequency of flare and remission; treatment history.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:50:55
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:50:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:50:09

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:35:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:35:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:34:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	31 Dec 2020 01:17:19
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	31 Dec 2020 01:17:19
User entered 'Pending additional medical records' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	31 Dec 2020 01:17:19
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Dec 2020 17:11:50
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 17:11:50

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Reviewed for Safety.	(b) (4)	06 Jan 2021 19:13:05
User entered 'USA-US091-2020-mRNA-1273-P301000008'	(b) (4), (b) (6)	06 Jan 2021 19:12:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Please verify as Illness visit results are all negative. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:41
	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 04:40:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 04:40:32
Data point term sent to Coder	System	31 Mar 2021 04:39:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
Data point term sent to Coder	System	31 Mar 2021 04:30:01
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
Query 'Please verify as Illness visit results are all negative. ' answered with 'will remove as source shows no positive covid-19 test results' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 04:28:49
User opened query 'Please verify as Illness visit results are all negative. ' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 15:38:23
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	05 Jan 2021 21:28:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Jan 2021 21:28:32
Data point term sent to Coder	System	05 Jan 2021 21:27:34
User entered 'COVID-19 Positive'	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered 'Yes (Y)'	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered 'Yes (Y)'	(b) (4)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	15 Apr 2021 19:14:57
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 21:02:26
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 21:02:26
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:10:39
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 12 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4) (u) (4), (b) (6)	09 Apr 2021 17:28:44
Query 'PV Query: COVID-19 symptoms have been reported starting on 12 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:25:22
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 14:25:03
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 14:25:03
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 12 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:10:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	31 Mar 2021 04:39:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '12 Dec 2020'	(b) (4) (u) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User entered empty.	System	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	22 Mar 2021 03:32:46
User entered 'No (N)' reason for change: Data Entry Error	System	16 Feb 2021 18:58:39
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Caitlin roll (b) (4)	16 Feb 2021 18:58:39
User entered 'Yes (Y)'		
	(b) (4), (b) (6)	16 Feb 2021 18:58:23
		05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(u) (4), (b) (6)	31 Mar 2021 04:38:26
	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
	(b) (4)	
User closed query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(u) (4), (b) (6)	17 Feb 2021 19:08:33
Query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Caitlin roll (b) (4)	16 Feb 2021 18:58:50
User entered '07 Jan 2021' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
	(b) (4), (b) (6)	
User opened query ' PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		14 Jan 2021 17:35:50
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User entered empty.	System	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Mar 2021 03:32:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 18:58:23
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
User opened query 'Data is required. Please complete.' (Site from System).	System	
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 21:28:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 21:28:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 21:28:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:28:02
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Jan 2021 21:28:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 21:28:02
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:27:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 21:27:45
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Jan 2021 21:27:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 21:27:45
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:27:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered '0'	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered empty.	(b) (4)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered empty.	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered '0'	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	17 Feb 2021 19:08:50
Query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(u) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	Caitlin roll (b) (4)	16 Feb 2021 18:58:55
Query 'Data is required. Please complete.' answered by data change (Site from System).		
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	16 Feb 2021 18:58:23
	System	16 Feb 2021 18:58:23
	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
User opened query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:34:36
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:27:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	17 Feb 2021 19:08:52
Query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Caitlin roll (b) (4)	16 Feb 2021 18:59:00
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 18:58:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 18:58:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
User opened query ' PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:34:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:27:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(u) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User closed query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' answered with 'changed as per query ' (Site from Safety).	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(u) (4), (b) (6)	05 Mar 2021 19:53:53
User opened query 'PV Query: As the last dose of mRNA-1273 or Placebo was given on 05 Oct 2020, please update the action taken with mRNA-1273 or Placebo from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 23:08:16
User closed query ' PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis and covid-19 positive.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 23:08:01
Query ' PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis and covid-19 positive.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 23:08:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 19:14:57
	(b) (4), (b) (6)	17 Feb 2021 19:08:59
	Caitlin roll (b) (4)	16 Feb 2021 18:59:05
	System	16 Feb 2021 18:58:23

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 18:58:23
User entered 'None (NONE)' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
User opened query ' PV Query: Please provide action taken with mRNA-1273 or placebo, along with dechallenge and rechallenge for event of acute hemorrhagic colitis and covid-19 positive.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:34:58
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 21:27:12
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User entered '0' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 23:08:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(u) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	System	16 Feb 2021 18:58:23
	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		
User entered '0'	System	05 Jan 2021 21:27:12
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered '0'	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(u) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	Milton Haber (b) (4)	22 Mar 2021 03:32:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(u) (4), (b) (6)	17 Feb 2021 19:09:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	Caitlin roll (b) (4)	16 Feb 2021 18:59:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	System	16 Feb 2021 18:58:23
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 18:58:23
User entered empty.	System	16 Feb 2021 18:58:23
	Caitlin roll (b) (4)	16 Feb 2021 18:58:23
	(b) (4), (b) (6)	14 Jan 2021 17:36:13
	System	05 Jan 2021 21:27:12
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint activated with code reason code Data required.	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	31 Mar 2021 04:29:17
User entered empty.	(b) (4)	22 Mar 2021 03:32:46
	(b) (4), (b) (6)	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'source shows subject tested positive for Covid-19 on 19DEC20' reason for change: Per Query Resolution	(b) (4) (u) (4), (b) (6)	31 Mar 2021 04:39:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:46
User closed query 'PV Query: COVID-19 diagnostic test result was updated to negative. Please confirm this is correct. If not, please update.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	17 Mar 2021 20:11:52
Query 'PV Query: COVID-19 diagnostic test result was updated to negative. Please confirm this is correct. If not, please update.' answered with 'Updated, Correct' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:25:40
User entered 'It has been resolved' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 14:25:32
User opened query 'PV Query: COVID-19 diagnostic test result was updated to negative. Please confirm this is correct. If not, please update.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:15:17
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:43:55
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 17:36:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Jan 2021 21:28:02

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Jan 2021 21:28:02
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Jan 2021 21:27:45
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:27:12

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User entered '0'	System	05 Jan 2021 21:28:17
User entered '1'	System	05 Jan 2021 21:27:45

US3572199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17
User entered 'l'	System	05 Jan 2021 21:27:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	31 Mar 2021 04:38:26
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 04:29:17

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:59:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	21 Feb 2021 00:33:53
User closed query 'Per source, Levofloxacin and Metronidazole are noted. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:33:51
User closed query 'Per source, multivitamins are noted. Please review and reconcile EDC.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 00:29:01
User closed query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:04:50
Query 'Per source, Levofloxacin and Metronidazole are noted. Please review and reconcile. ' answered with 'updated as per source ' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 17:48:15
Query 'Per source, multivitamins are noted. Please review and reconcile EDC.' answered with 'updated as per subject ' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 17:48:08
Query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' answered with 'as per query resolution' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 16:33:56
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Feb 2021 16:33:47
User opened query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:55:51

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 20:02:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 20:02:46
User opened query 'Per source, Levofloxacin and Metronidazole are noted. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:42:15
User opened query 'Per source, multivitamins are noted. Please review and reconcile EDC.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 15:35:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:34:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica McDowell (b) (4)	25 Sep 2020 13:17:54
User entered 'No (N)'	Jessica McDowell (b) (4)	11 Sep 2020 17:46:04

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 01:33:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 01:33:23
Data point term sent to Coder	System	31 Dec 2020 01:32:58
Coding entries removed.	Maria Candelario (b) (4)	31 Dec 2020 01:32:56
User entered 'Escitalopram' reason for change: Data Entry Error	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Maria Candelario (b) (4)	31 Dec 2020 01:32:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	25 Sep 2020 13:19:50
User entered 'lexapro'	(b) (4)	
	Coder Import (b) (4)	25 Sep 2020 13:19:50
	System	25 Sep 2020 13:19:03
	Jessica McDowell (b) (4)	25 Sep 2020 13:18:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 03:42:42
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'per source not an AE. per source cannot find Anxiety as part of medical history for this antidepressant' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:04:08
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:18:50
User entered 'anxiety'	Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '10'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'mg (mg)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'once daily (QD)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Oral (ORAL)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '24 Sep 2020'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 13:18:37

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 16:00:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:00:30
Data point term sent to Coder	System	13 Oct 2020 15:19:24
User entered 'gentamicin eye drops'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'scratch to right eye'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'l'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Other (OTHER)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'drop to affected eye'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'once daily (QD)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '2 Oct 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '12 Oct 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 05:36:25
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'Data updated ' (Site from DM).	Maria Candelario (b) (4) (b) (4)	31 Dec 2020 01:23:03
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	31 Dec 2020 01:22:48
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:24:30
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
User entered 'l'	System	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
User entered 'I'	System	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:00:53
User entered '804 (804)'	System	13 Oct 2020 15:19:12

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:23:01
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'CM box checked on AE eCRG' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:45:51
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:50:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Jan 2021 19:36:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Jan 2021 19:36:34
Data point term sent to Coder	System	31 Dec 2020 01:22:58
User entered 'Loperamide'	Maria Candelario (b) (4) (b) (4)	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Acute Hemorrhagic Colitis'	(b) (4) Maria Candelario (b) (4) (b) (4)	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '2'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'mg (mg)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'other (OTHER)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'every 4 hrs as needed'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Oral (ORAL)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '19 Dec 2020'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	31 Dec 2020 01:22:22
	(b) (4)	

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:22:22

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 09:57:23
' (Site from DM).		
Query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	04 Mar 2021 23:09:56
' answered with 'reconciled ' (Site from DM).		
User opened query 'Per DM CLR: This Conmed is given for the AE#3. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	03 Mar 2021 04:15:40
' (Site from DM).		
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 00:10:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 00:10:59
Data point term sent to Coder	System	17 Feb 2021 17:42:27
User entered 'Levaquin'	(b) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'COVID-19 positive'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '500'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '24 Dec 2020'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '30 Dec 2020'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
User entered 'I'	System	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
User entered 'I'	System	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:05
User entered '804 (804)'	System	17 Feb 2021 17:41:48

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:18:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:18:00
Data point term sent to Coder	System	17 Feb 2021 17:43:31
User entered 'Flagyl'	(b) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of DIARRHEA during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 09:57:12
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of DIARRHEA during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Per PI in source, "She also is taking metronidazole 500 mg Q8 hours. She is continuing the metronidazole and has one dose left. She had one episode of bloody stool yesterday. She was Covid positive on December 19 and was hospitalized for that and is home.'" (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:25:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication of DIARRHEA during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:16:28
User entered 'Colitis/Diarrhea'	(b) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '500'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'three times daily (TID)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '24 Dec 2020'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '29 Dec 2020'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
User entered '3'	System	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
User entered 'I'	System	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:01:11
User entered '804 (804)'	System	17 Feb 2021 17:43:10

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 17:49:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 17:49:01
Data point term sent to Coder	System	17 Feb 2021 17:48:44
User entered 'Multivitamin'	(b) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 10:01:16
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 23:27:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 23:27:29
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 19:30:13
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'supplement'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:10:39
User closed query 'Per CDM RQ: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Apr 2021 03:19:18
Query 'Per CDM RQ: If Dose per administration is Unknown, please record as UNK per CCGs.' answered with 'unknown dose' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 04:12:26
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 04:11:46
User entered 'UNK' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Apr 2021 04:11:46
User opened query 'Per CDM RQ: If Dose per administration is Unknown, please record as UNK per CCGs.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:02:59
User closed query 'Per DM CLR: Please remove the extraneous data (ie. TABLET) in the Dose field as units should be in numerical form as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:02:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (u) (4), (b) (6)	03 Apr 2021 04:16:47
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Jessica McDowell (b) (4)	02 Apr 2021 15:53:57
Query 'Per DM CLR: Please remove the extraneous data (ie. TABLET) in the Dose field as units should be in numerical form as appropriate.' answered with 'unknown' (Site from DM).	Jessica McDowell (b) (4)	02 Apr 2021 15:53:42
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 15:53:32
User entered empty; reason for change Per Query Resolution	Jessica McDowell (b) (4)	02 Apr 2021 15:53:32
User opened query 'Per DM CLR: Please remove the extraneous data (ie. TABLET) in the Dose field as units should be in numerical form as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:47:24
User closed query 'Per CDM RQ: Please update the Dose unit appropriately as dose is updated as UNK.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 05:35:19

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per CDM RQ: Please update the Dose unit appropriately as dose is updated as UNK.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:56:35
User entered 'tablet' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 14:46:24
User opened query 'Per CDM RQ: Please update the Dose unit appropriately as dose is updated as UNK.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:09:26
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:09:26
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 02:34:11
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 02:34:00
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:03:00
User entered 'unknown'	(b) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:10:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(u) (4), (b) (6)	09 Apr 2021 09:41:06
User closed query 'Per CDM: Dose per administration is updated as UNK. Please review and update dose unit accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:41:04
Query 'Data is required. Please complete.' answered with 'UNK' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 16:04:10
Query 'Per CDM: Dose per administration is updated as UNK. Please review and update dose unit accordingly.' answered with 'UNK' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:04:05
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 16:03:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:03:41
User opened query 'Per CDM: Dose per administration is updated as UNK. Please review and update dose unit accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 03:20:23
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 04:12:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 04:12:03
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 04:12:03
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 04:11:46
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 04:11:46
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 04:11:46
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'mg (mg)'	(b) (4)	
	(u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'un UNK 2017'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered '0'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered empty.	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Feb 2021 17:47:44

US3572199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:19:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:51:15
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:16
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	08 Jan 2021 20:02:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '31/Dec/2020 13:36'	(b) (4) System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'l'	(b) (4), (b) (6)	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '04/Jan/2021 15:25'	(b) (4) System	04 Jan 2021 15:25:37

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:29:51
User entered 'l'	(b) (4), (b) (6)	04 Jan 2021 15:25:37

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '06/Jan/2021 14:16'	(b) (4) System	06 Jan 2021 19:16:45

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:29:51
User entered 'l'	(b) (4), (b) (6)	06 Jan 2021 19:16:45

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '03/Feb/2021 09:29'	(b) (4) System	03 Feb 2021 14:29:48

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:29:51
User entered 'l'	(b) (4), (b) (6)	03 Feb 2021 14:29:48

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '17/Feb/2021 14:07'	(b) (4) System	17 Feb 2021 19:08:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	05 Mar 2021 19:54:17
User entered 'l'	(b) (4), (b) (6)	17 Feb 2021 19:08:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '17/Feb/2021 14:10'	(b) (4) System	17 Feb 2021 19:10:29

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	05 Mar 2021 19:54:17
User entered 'l'	(b) (4), (b) (6)	17 Feb 2021 19:10:29

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '05/Mar/2021 14:54'	(b) (4) System	05 Mar 2021 19:54:39

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'I'	(b) (4) (u) (4), (b) (6)	05 Mar 2021 19:54:39

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '17/Mar/2021 16:12'	(b) (4) System	17 Mar 2021 20:12:11

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:12:11

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '22/Mar/2021 14:27'	(b) (4) System	22 Mar 2021 18:27:35

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:27:35

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '22/Mar/2021 14:27'	(b) (4) System	22 Mar 2021 18:27:35

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:27:35

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:19:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered '31/Mar/2021 13:03'	(b) (4) System	31 Mar 2021 20:03:20

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:19:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:03:20

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'USA-US091-2020-MRNA-1273-P301000008'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
Un-reviewed for Safety.	System	04 Jan 2021 06:59:26
User entered 'Yes (Y)'	System	04 Jan 2021 06:59:26
Reviewed for Safety.	(b) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

US3572199

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'No (N)'	System	31 Dec 2020 18:36:00

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Milton'	System	31 Dec 2020 18:36:00

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Haber'	System	31 Dec 2020 18:36:00

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Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '2344 Laguna Del Mar, Suite 201'	System	31 Dec 2020 18:36:00

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[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'Laredo'	System	31 Dec 2020 18:36:00

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered 'TX'	System	31 Dec 2020 18:36:00

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Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 18:36:43
User entered '78041'	System	31 Dec 2020 18:36:00

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:45:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 15:25:24
User entered 'US'	System	31 Dec 2020 18:36:53

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	09 Apr 2021 17:30:52
User entered '11'	System	31 Mar 2021 20:03:20
User entered '10'	System	22 Mar 2021 18:27:35
User entered '9'	System	22 Mar 2021 18:27:35
User entered '8'	System	17 Mar 2021 20:12:11
User entered '7'	System	05 Mar 2021 19:54:39
User entered '6'	System	17 Feb 2021 19:10:29
User entered '5'	System	17 Feb 2021 19:08:00
User entered '4'	System	03 Feb 2021 14:29:48
User entered '3'	System	06 Jan 2021 19:16:45
User entered '2'	System	04 Jan 2021 15:25:37
User entered '1'	System	31 Dec 2020 18:36:53

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Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (12)

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[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:10:39
User entered '09/Apr/2021 10:30'	(b) (4) System	09 Apr 2021 17:30:52

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Folder: SAE USA-US091-2020-MRNA-1273-P301000008

Form: Safety Report Form (12)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 03:50:05
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:10:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:30:52