

US3652039 (Prod: Weill Cornell Medical College)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:59:05

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US3652039

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

[Participant ID](#)

US3652039

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

US3652039

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 SEP 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input type="radio"/> Male <input checked="" 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

US3652039

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Date of Informed Consent (*dd MMM yyyy*) 24 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3652039

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Condition	VASOVAGAL RESPONSE
Start date (dd MMM yyyy)	29 SEP 2020
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)	29 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:00:01

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Height (xxx.x) _____

Weight (xxx.x) _____

BMI (xxx.x) _____

BMI units _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

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 MARRIED AND LIVES WITH (b) (6) PHYSICIAN, SEEING COVID+1 PATIENTS.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Apr 2021 13:00:00

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Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

What was the date of randomization? (dd MMM yyyy) 29 SEP 2020

What was the participant's randomization number? 115443

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) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Height	166.2 cm
Weight	72.1 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Height	166.2 cm
Weight	72.1 kg
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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:31
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 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) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Height	166.2 cm
Weight	72.1 kg
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:10 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:10
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

29 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 11:34

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) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	29 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:18 (24 HR)
Collection date and time (derived)	29 SEP 2020 11:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Collection date (<i>dd MMM yyyy</i>)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:32	29 SEP 2020 11:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

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: 11 Aug 2021 22:59:05

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °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 29 SEP 2020 12:09

PC Open Date & Time 29 SEP 2020 11:54

PC Close Date & Time 29 SEP 2020 14:24

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °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 29 SEP 2020 20:01
PC Open Date & Time 29 SEP 2020 15:19
PC Close Date & Time 30 SEP 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 22:30
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 OCT 2020 22:05

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 OCT 2020 19:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 03 OCT 2020 12:00
PC Close Date & Time 04 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

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** 97.9 °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	04 OCT 2020 22:36
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

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

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 00:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

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

29 SEP 2020 12:07

PC Open Date & Time

29 SEP 2020 11:54

PC Close Date & Time

29 SEP 2020 14:24

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

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

29 SEP 2020 20:02

PC Open Date & Time

29 SEP 2020 15:19

PC Close Date & Time

30 SEP 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	30 SEP 2020 22:31
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	01 OCT 2020 22:05
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	02 OCT 2020 19:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

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

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

04 OCT 2020 22:36

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	06 OCT 2020 00:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

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

No

Yes

PC Time stamp	29 SEP 2020 12:07
PC Open Date & Time	29 SEP 2020 11:54
PC Close Date & Time	29 SEP 2020 14:24

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

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

No

Yes

PC Time stamp	29 SEP 2020 20:03
PC Open Date & Time	29 SEP 2020 15:19
PC Close Date & Time	30 SEP 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 22:31
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

	Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 22:05
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 19:53
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

Yes

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

	Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 22:36
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 07 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3652039

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

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 _____

US3652039

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

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 _____

US3652039

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3652039

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

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.

US3652039

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3652039

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 61

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 68

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 75

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 82

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 89

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 28 DEC 2020 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°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"/>

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 JAN 2021 15:51:30
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 JAN 2021 10:31:25
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 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	31 JAN 2021 10:38:15
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 131

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#) 08 FEB 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 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	13 FEB 2021 14:54:38
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 <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	20 FEB 2021 10:06:31
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 <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	27 FEB 2021 15:03:00
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 08 MAR 2021 11:50:30

Patient Cloud Open Date & Time 04 MAR 2021 00:01

Patient Cloud Close Date & Time 08 MAR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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	12 MAR 2021 09:06:26
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 180

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 194

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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	19 APR 2021 09:51:46
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 22 APR 2021 22:24:30

Patient Cloud Open Date & Time 22 APR 2021 00:01

Patient Cloud Close Date & Time 26 APR 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 16 AUG 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 30 AUG 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 383

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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
Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 418

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 425

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

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

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

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

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

- Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)
- Chills
- Cough
- Shortness of breath
- Difficulty breathing
- Fatigue
- Muscle aches
- Body aches
- Headache
- New loss of taste
- New loss of smell
- Sore throat
- Congestion
- Runny nose
- Nausea
- Vomiting
- Diarrhea

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 06 DEC 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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
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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 27 DEC 2021 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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
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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#) 03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 07 FEB 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 14 FEB 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 544

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 06 JUN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 19 SEP 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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
Yes

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 Yes

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#) 14 NOV 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 782

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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

[Patient Cloud Close Date & Time](#)

05 DEC 2022 23:59

US3652039

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:59:05

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 23:04:11

US3652039

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:12

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:28:30

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3652039

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

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.

US3652039

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3652039

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Date of Contact	27 OCT 2020
Time of Contact	13:20
Date and Time of Contact (derived)	27 OCT 2020 13:20
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	27 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	99.3 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

291 of 2720

EAB) (1725)

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 28 OCT 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 37 C

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	29 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	36.4 C
-------------	--------

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

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

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

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 30 OCT 2020

Assessment Not Done False

O2 Saturation 100 %

O2 Saturation Units %

Temperature 36.7 C

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	31 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

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US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 01 NOV 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.3 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 25 OCT 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

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

Shortness of Breath

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

Difficulty Breathing

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 26 OCT 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

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

Difficulty Breathing

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 04 NOV 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.2 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

Body Aches

None

Mild

Moderate

Severe

Not Done

Headache

None

Mild

Moderate

Severe

Not Done

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 type="checkbox"/>
Day 9	<input checked="" 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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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 02 NOV 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 96.5 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	05 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	07 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 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 checked="" 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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	08 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

None

Mild

Moderate

Severe

Not Done

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

Nausea

None

Mild

Moderate

Severe

Not Done

Vomiting

None

Mild

Moderate

Severe

Not Done

Diarrhea

None

Mild

Moderate

Severe

Not Done

Sore Throat

None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 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 checked="" 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"/>

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	09 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

	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	01 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Date of Visit 27 OCT 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 27 OCT 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 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 _____

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 _____

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

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 _____

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:58

Generated On: 11 Aug 2021 22:59:05

[Generate Next COVID-19 Assessment](#)

Yes

No

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 OCT 2020
Day 5	Yes	31 OCT 2020
Day 7	Yes	02 NOV 2020
Day 9	Yes	04 NOV 2020
Day 14	Yes	09 NOV 2020
Day 21	Yes	16 NOV 2020
Day 28	Yes	01 DEC 2020

US3652039

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 27 OCT 2020

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

Folder OID SICKD1

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	99.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFORMATION NOT SPECIFIED.
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3652039

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3652039

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

27 OCT 2020

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SICKD28

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:28 (24 HR)
Vital Signs Date and Time (derived)	01 DEC 2020 14:28
Height (<i>xxx.x</i>)	166.2 cm
Weight (<i>xxx.x</i>)	72.1 kg
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

01 DEC 2020

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

US3652039

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

01 DEC 2020

US3652039

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 JAN 2021

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

Folder OID UNBLND_DECIDE

US3652039

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3652039

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Height	166 cm
Weight	72.1 kg
BMI (xxx.x)	26.16490

US3652039

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Height	166 cm
Weight	72.1 kg
BMI (xxx.x)	26.16490
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)	13 JAN 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 10:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3652039

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Height	166 cm
Weight	72.1 kg
BMI (xxx.x)	26.16490
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)	13 JAN 2021
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 12:36
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3652039

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3652039

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:28:30

Generated On: 11 Aug 2021 22:59:05

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 11:03

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

What was the frequency of the study treatment dosing? ONCE

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

US3652039

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 JAN 2021

Collection time (*00:00-23:59*) 10:40 (24 HR)

Collection date and time (derived) 13 JAN 2021 10:40

US3652039

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 JAN 2021
Collection time (<i>00:00 - 23:59</i>)	10:44
Collection Date and Time (derived)	13 JAN 2021 10:44

US3652039

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 10 FEB 2021

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

Folder OID OLD29

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

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 (<i>dd MMM yyyy</i>)	10 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:38 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:38
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

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 (<i>dd MMM yyyy</i>)	10 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:20 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 11:20
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3652039

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3652039

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

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 FEB 2021

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:49

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

US3652039

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3652039

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3652039

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 MAR 2021

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

Folder OID OLD57

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 11:35
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3652039

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3652039

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	18 MAR 2021
Collection time (<i>00:00-23:59</i>)	11:49 (24 HR)
Collection date and time (derived)	18 MAR 2021 11:49

US3652039

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 21:41:19

Generated On: 11 Aug 2021 22:59:05

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 OCT 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 11 Aug 2021 22:59:05

AEID USA-US132-2020-MRNA-1273-P30
1000002

Adverse event COVID-19 (SARS-COV-2
CONFIRMED 10/27/2020)

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) 25 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) 03 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 11 Aug 2021 22:59:05

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 11 Aug 2021 22:59:05

PARTICIPANT IS A 33YR OLD
MALE ENROLLED ON 9/29/2020.

HE HAD NO SIGNIFICANT
MEDICAL HISTORY AND
REPORTED HIMSELF AS AT
RISK OF COVID FROM HIS
SPOUSE'S WORK WITH COVID+
PATIENTS AS WELL AS LIVING
IN HOUSING WITH >5 PEOPLE.

HE RECEIVED HIS FIRST
INJECTION ON 9/29/2020. HIS
SECOND INJECTION WAS
SCHEDULED FOR 10/27/2020.
HOWEVER, ON 10/26/2020 THE
PARTICIPANT REACHED OUT

TO STUDY TO REPORT
COVID-LIKE SYMPTOMS POST
A KNOWN EXPOSURE. HE

REPORTED THAT THE FAMILY'S
NANNY TESTED POSITIVE FOR
COVID ON 10/21/2020 AND THE
PT'S 8 MONTH OLD DAUGHTER

TESTED POSITIVE ON
10/22/2020. PT WAS

ASYMPTOMATIC AT THAT
TIME AND TESTED NEGATIVE
VIA A RAPID TEST AND A PCR

ON 10/23/2020 AT LOCAL
URGENT CARE. ON 10/25/2020,
HIS WIFE TESTED POSITIVE.

PARTICIPANT WAS SEEN ON
10/27/2020 BY THE STUDY
CLINICIANS. AT THE TIME OF

THE VISIT HE REPORTED
FATIGUE, BODY ACHES,

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Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES, COUGH, CHILLS, AND SHORTNESS OF BREATH ALL MILD TO MODERATE. HIS VITALS WERE STABLE: T: 99.3, 104/72, HR 80, O2 SAT 100%. HE WAS RETESTED BY VIRACOR PCR (POSITIVE REPORT 10/31/2020). NO MEDICAL INTERVENTION FOR HIS SYMPTOMS WAS REQUIRED AT THIS VISIT OR THEREAFTER. HE DID TAKE ADVIL AND TYLENOL FOR HIS SYMPTOMS. PT WAS MONITORED VIA TELEVISITS FOR THE NEXT 14 DAYS. DURING THIS TIME HIS O2 SATS REMAINED AT 99%, HIS TEMPERATURE REMAINED NORMAL AND HE REQUIRED NO MEDICAL INTERVENTION. HE DID ADDITIONALLY REPORT SORE THROAT. HE REPORTED SYMPTOM RESOLUTION BY 11/5/2020. SALIVA WAS COLLECTED PER PROTOCOL ON DAY 3, 5, 7, 9, 14, AND 21. SALIVA DAY 3 AND 5 RETURNED DETECTED. SALIVA DAY 7 AND 9 REPORTED AS SNOT DETECTED. SALIVA DAY 14 AND 21 HAVE NOT RESULTED. A 28 DAY CONVALESCENT VISIT IS SCHEDULED FOR 11/24/2020.

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 (3)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	LOWER LIP SWELLING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	11:20 (24 HR)
AE start date and time (derived)	13 JAN 2021 11:20
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	FEVER (POST OL AE)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

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Folder: Adverse Events

Form: Adverse Events (5)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	CHILLS (POST OL AE)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	GENERALIZED MUSCLE ACHE (POST OL AE)
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input checked="" type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (6)

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

Generated On: 11 Aug 2021 22:59:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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 Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	FATIGUE (POST OL AE)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 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 type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	HEADACHE (POST OL AE)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	PAIN AT INJECTION SITE (LEFT ARM, POST OL AE)
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	15 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" 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 checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (9)

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

Generated On: 11 Aug 2021 22:59:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	SHORTNESS OF BREATH (POST OL AE)
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" 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 checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (10)

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

Generated On: 11 Aug 2021 22:59:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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 Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (11)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	SORE THROAT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

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

Generated On: 11 Aug 2021 22:59:05

AEID _____

Adverse event LOWER LIP SWELLING

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) 10 FEB 2021

Start time (00:00-23:59) 11:14 (24 HR)

AE start date and time (derived) 10 FEB 2021 11:14

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

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Folder: Adverse Events

Form: Adverse Events (12)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (13)

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

Generated On: 11 Aug 2021 22:59:05

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 FEB 2021
Start time (00:00-23:59)	22:00 (24 HR)
AE start date and time (derived)	10 FEB 2021 22:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	22:00 (24 HR)
AE End Date and Time (derived)	11 FEB 2021 22:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (13)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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 <input type="radio"/> 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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (14)

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

Generated On: 11 Aug 2021 22:59:05

AEID

Adverse event FATIGUE

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) 10 FEB 2021

Start time (00:00-23:59) 22:00 (24 HR)

AE start date and time (derived) 10 FEB 2021 22:00

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 11 FEB 2021

End time (00:00-23:59) 22:00 (24 HR)

AE End Date and Time (derived) 11 FEB 2021 22:00

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (14)

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

Generated On: 11 Aug 2021 22:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input 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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 12:59:18

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication MULTIVITAMIN ADULT

Prophylaxis Yes
No

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) _____

Start date completely unknown True

Ongoing? Yes No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802 803 804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication ADVIL

Prophylaxis Yes
No

Indication HEADACHE PAIN (EDIARY SYMPTOMS)

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	01 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)	01 OCT 2020
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication ADVIL

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 16 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 16 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication COVID-19 SYMPTOMS

Dose per administration 400

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) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 25 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 27 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication COVID-19 SYMPTOMS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 25 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 27 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication COVID-19 SYMPTOMS

Dose per administration 400

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 29 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 29 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802

803

804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication COVID-19 SYMPTOMS (SORE THROAT)

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 28 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication COVID-19 SYMPTOMS (SORE THROAT)

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	30 OCT 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="checkbox"/>
	803 <input type="checkbox"/>
	804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication FINASTERIDE

Prophylaxis Yes
No

Indication HAIR LOSS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration UNKNOWN

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 10 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication ADVIL

Prophylaxis Yes
No

Indication MUSCLE ACHE (POST OL AE)

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 13 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication FEVER (POST OL AE)

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)

442 of 2720

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 13 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 14 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 2720

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

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*) 10 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3652039

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 12:59:18

Generated On: 11 Aug 2021 22:59:05

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3652039

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 12:59:59

Generated On: 11 Aug 2021 22:59:05

Date of dosing discontinuation (dd MMM yyyy) 28 OCT 2020

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Due to SARS-COV-2

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

US3652039

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:59:05

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

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

SAEID	USA-US132-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

SAEID	USA-US132-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 13:00:00

Generated On: 11 Aug 2021 22:59:05

SAEID	USA-US132-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/NOV/2020 17:37
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.	<input checked="" type="checkbox"/> True

Audit

US3652039 (Prod: Weill Cornell Medical College)

US3652039

Form: Participant Creation

Generated On: 11 Aug 2021 22:59:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'US3652039'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	25 Sep 2020 15:04:31

US3652039

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per CDM: Please complete all applicable forms for this visit. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:51:48
Query 'Per CDM: Please complete all applicable forms for this visit. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	02 Oct 2020 04:12:41
User opened query 'Per CDM: Please complete all applicable forms for this visit. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:55:10
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	29 Sep 2020 15:32:50

US3652039

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 15:04:32

US3652039

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Home (Home)'	Sarah Galloway (b) (4)	29 Sep 2020 15:32:50

US3652039

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered 'SCRN'	System	29 Sep 2020 15:32:50

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 15:04:33

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '33'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered 'YEARS'	System	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered '33'	System	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Male (M)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '1'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:10

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '24 Sep 2020'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered 'Sep 2020'	System	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered '2020'	System	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Amendment 3 (3)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:28

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 15:04:32

US3652039

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered '1'	System	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:59:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	02 Oct 2020 04:19:44
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:20

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal reaction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 06:50:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 06:50:45
Data point term sent to Coder	System	02 Oct 2020 04:20:15
User entered 'vasovagal response'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per sponsor review, medical history start date is the same first IP dose date. Please confirm if event began prior to dosing. If confirmed no, consider moving event to AE CRF per protocol. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:36:17
Query 'Per CDM: Per sponsor review, medical history start date is the same first IP dose date. Please confirm if event began prior to dosing. If confirmed no, consider moving event to AE CRF per protocol. ' answered with 'Response occurred 11:10AM - 11:20AM (prior to IP)' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:40:36
User opened query 'Per CDM: Per sponsor review, medical history start date is the same first IP dose date. Please confirm if event began prior to dosing. If confirmed no, consider moving event to AE CRF per protocol. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:57:13
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	02 Oct 2020 04:19:58
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	22 Oct 2020 02:57:15
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	02 Oct 2020 04:19:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

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

Audit	User	Time (GMT)
User entered '29 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Oct 2020 02:57:15
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Stop date completely unknown

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

Start Year (derived)

Audit	User	Time (GMT)
User entered '2020'	System	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	22 Oct 2020 02:57:15
User entered empty.	System	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	22 Oct 2020 02:57:15
User entered empty.	System	02 Oct 2020 04:19:58

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01
DataPoint set to visible.	(b) (4) System	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01
DataPoint set to visible.	(b) (4) System	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01
DataPoint set to visible.	System	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01
DataPoint set to visible.	System	29 Sep 2020 15:33:35

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User entered empty.	System	02 Oct 2020 04:13:01

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22

US3652039

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22

US3652039

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:11

US3652039

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:11

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Married and lives with (b) (6) (b) (6) physician, seeing COVID+1 patients.'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '1'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

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)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:13:56

US3652039

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:30

US3652039

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:15:30

US3652039

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:30

US3652039

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'VISIT1'	System	02 Oct 2020 04:15:30

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 15:17:54

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '115443'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 15:17:54

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 15:17:54

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

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)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

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)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55

US3652039

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:05

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:55
DataPoint set to visible.	(b) (4) System	29 Sep 2020 15:33:28

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '166.2' cm	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '72.1' kg	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '166.2' cm	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '72.1' kg	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '10:31'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '29 Sep 2020 10:31'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '36.6' C	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '65'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'bpm'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '14'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'breaths/min'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '117'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'mmHg'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '80'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'mmHg'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '166.2' cm	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '72.1' kg	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '12:10'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '29 Sep 2020 12:10'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '36.7' C	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '56'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'bpm'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '14'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'breaths/min'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '117'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'mmHg'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '77'	Jiamin Li (b) (4)	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'mmHg'	System	02 Oct 2020 04:17:57

US3652039

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:18:16

US3652039

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:18:16

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

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)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '11:34'	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '29 Sep 2020 11:34'	System	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Left Arm (LEFT ARM)'	Sarah Galloway (b) (4)	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'ONCE'	System	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 15:41:00

US3652039

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:19:04

US3652039

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:19:04

US3652039

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '11:18'	Jiamin Li (b) (4)	02 Oct 2020 04:19:04

US3652039

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '29 Sep 2020 11:18'	System	02 Oct 2020 04:19:04

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '29 Sep 2020'	Jiamin Li (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '11:32'	Jiamin Li (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '29 Sep 2020 11:32'	System	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	02 Oct 2020 04:18:25

US3652039

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User closed query 'Per CDM RQ: Response noted as 'Visits are recorded?' however, no data is recorded in V2D29, please review and record the data, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 09:40:50
Query 'Per CDM RQ: Response noted as 'Visits are recorded?' however, no data is recorded in V2D29, please review and record the data, else clarify.' answered with 'Participant did not receive second dose due to COVID-19. ' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:43:01
User opened query 'Per CDM RQ: Response noted as 'Visits are recorded?' however, no data is recorded in V2D29, please review and record the data, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:35:45
User closed query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 22:11:57
Query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' answered with 'Visits are recorded?' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:31:51
User opened query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:59:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:18:41

US3652039

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	02 Oct 2020 04:18:41

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:08:13', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '6bee0ac4-50ca-4217-bbdd-94c133757d3d' User entered 'Yes (Y)'	System	29 Sep 2020 16:09:31
	System	29 Sep 2020 16:09:31

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:09:06', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '6bee0ac4-50ca-4217-bbdd-94c133757d3d' User entered '98.0'	System	29 Sep 2020 16:09:31
	System	29 Sep 2020 16:09:31

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:09:26', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '6bee0ac4-50ca-4217-bbdd-94c133757d3d' User entered 'No (N)'	System	29 Sep 2020 16:09:31
	System	29 Sep 2020 16:09:31

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:09:29', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '6bee0ac4-50ca-4217-bbdd-94c133757d3d' User entered '29 Sep 2020 12:09'	System	29 Sep 2020 16:09:31
	System	29 Sep 2020 16:09:31

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 11:54'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 14:24'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:01:38', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f2e20b8a-86d0-41a8-88ec-2eceb4bc36'	System	30 Sep 2020 00:01:51
User entered 'Yes (Y)'	System	30 Sep 2020 00:01:51

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:01:42', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f2e20b8a-86d0-41a8-88ec-2eceb4bc36'	System	30 Sep 2020 00:01:51
User entered '98.2'	System	30 Sep 2020 00:01:51

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:01:45', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f2e20b8a-86d0-41a8-88ec-2eceb4bc36'	System	30 Sep 2020 00:01:51
User entered 'No (N)'	System	30 Sep 2020 00:01:51

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:01:49', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f2e20b8a-86d0-41a8-88ec-2eceb4bc36'	System	30 Sep 2020 00:01:51
User entered '29 Sep 2020 20:01'	System	30 Sep 2020 00:01:51

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 15:19'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 2'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:30:43', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '88e68373-9de9-4168-8af5-22c503710efc' User entered 'Yes (Y)'	System	01 Oct 2020 02:30:56
	System	01 Oct 2020 02:30:56

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:30:47', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '88e68373-9de9-4168-8af5-22c503710efc' User entered '98.0'	System	01 Oct 2020 02:30:56
	System	01 Oct 2020 02:30:56

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:30:52', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '88e68373-9de9-4168-8af5-22c503710efc'	System	01 Oct 2020 02:30:56
User entered 'No (N)'	System	01 Oct 2020 02:30:56

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:30:54', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '88e68373-9de9-4168-8af5-22c503710efc'	System	01 Oct 2020 02:30:56
User entered '30 Sep 2020 22:30'	System	01 Oct 2020 02:30:56

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 3'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:04:31', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c' User entered 'Yes (Y)'	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:04:40', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c' User entered '97.3'	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:04:48', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c' User entered 'Yes (Y)'	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Advil, recorded.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 06:33:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jiamin Li (b) (4)	22 Oct 2020 03:00:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:01', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c'	(b) (4)	
User entered '1'	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:01', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c' User entered '0'	System	02 Oct 2020 02:05:09
	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:07', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a8d670fb-2552-4f79-ba12-d08634b9044c'	System	02 Oct 2020 02:05:09
User entered '01 Oct 2020 22:05'	System	02 Oct 2020 02:05:09

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 4'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:52:42', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '260851bf-3da3-452c-957c-d723f9283e67'	System	02 Oct 2020 23:53:08
User entered 'Yes (Y)'	System	02 Oct 2020 23:53:08

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:52:45', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '260851bf-3da3-452c-957c-d723f9283e67' User entered '97.6'	System	02 Oct 2020 23:53:08
	System	02 Oct 2020 23:53:08

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '260851bf-3da3-452c-957c-d723f9283e67'	System	02 Oct 2020 23:53:08
User entered 'No (N)'	System	02 Oct 2020 23:53:08

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:02', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '260851bf-3da3-452c-957c-d723f9283e67' User entered '02 Oct 2020 19:53'	System	02 Oct 2020 23:53:08
	System	02 Oct 2020 23:53:08

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 5'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 6'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:35:50', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '62bd5ceb-3ef8-424c-bf92-c22bc3811776'	System	05 Oct 2020 02:36:20
User entered 'Yes (Y)'	System	05 Oct 2020 02:36:20

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '62bd5ceb-3ef8-424c-bf92-c22bc3811776' User entered '97.9'	System	05 Oct 2020 02:36:20
	System	05 Oct 2020 02:36:20

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:14', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '62bd5ceb-3ef8-424c-bf92-c22bc3811776'	System	05 Oct 2020 02:36:20
User entered 'No (N)'	System	05 Oct 2020 02:36:20

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:16', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '62bd5ceb-3ef8-424c-bf92-c22bc3811776'	System	05 Oct 2020 02:36:20
User entered '04 Oct 2020 22:36'	System	05 Oct 2020 02:36:20

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 7'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:34', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '2b47a774-855d-4b14-988d-143956d620b9'	System	06 Oct 2020 04:00:41
User entered 'No (N)'	System	06 Oct 2020 04:00:41

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:37', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '2b47a774-855d-4b14-988d-143956d620b9'	System	06 Oct 2020 04:00:41
User entered 'No (N)'	System	06 Oct 2020 04:00:41

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:39', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '2b47a774-855d-4b14-988d-143956d620b9'	System	06 Oct 2020 04:00:41
User entered '06 Oct 2020 00:00'	System	06 Oct 2020 04:00:41

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:06:30', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7c177d98-8567-47e2-9a8d-07187acee027'	System	29 Sep 2020 16:07:15
User entered 'None (1)'	System	29 Sep 2020 16:07:15

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:06:41', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7c177d98-8567-47e2-9a8d-07187acee027'	System	29 Sep 2020 16:07:15
User entered 'No (N)'	System	29 Sep 2020 16:07:15

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:06:48', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7c177d98-8567-47e2-9a8d-07187acee027'	System	29 Sep 2020 16:07:15
User entered 'No (N)'	System	29 Sep 2020 16:07:15

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:08', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7c177d98-8567-47e2-9a8d-07187acee027'	System	29 Sep 2020 16:07:15
User entered 'None (1)'	System	29 Sep 2020 16:07:15

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7c177d98-8567-47e2-9a8d-07187acee027' User entered '29 Sep 2020 12:07'	System	29 Sep 2020 16:07:15
	System	29 Sep 2020 16:07:15

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 11:54'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 14:24'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:02', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b977100e-489f-495d-8e8e-2f22011fb2f3'	System	30 Sep 2020 00:02:35
User entered 'None (1)'	System	30 Sep 2020 00:02:35

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:05', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b977100e-489f-495d-8e8e-2f22011fb2f3'	System	30 Sep 2020 00:02:35
User entered 'No (N)'	System	30 Sep 2020 00:02:35

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:19', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b977100e-489f-495d-8e8e-2f22011fb2f3'	System	30 Sep 2020 00:02:35
User entered 'No (N)'	System	30 Sep 2020 00:02:35

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:27', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b977100e-489f-495d-8e8e-2f22011fb2f3'	System	30 Sep 2020 00:02:35
User entered 'None (1)'	System	30 Sep 2020 00:02:35

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:32', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b977100e-489f-495d-8e8e-2f22011fb2f3'	System	30 Sep 2020 00:02:35
User entered '29 Sep 2020 20:02'	System	30 Sep 2020 00:02:35

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 15:19'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 2'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:30:58', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '22036cc4-464e-4131-947a-0b6d89dcac2a'	System	01 Oct 2020 02:31:16
User entered 'None (1)'	System	01 Oct 2020 02:31:16

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:01', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '22036cc4-464e-4131-947a-0b6d89dcac2a'	System	01 Oct 2020 02:31:16
User entered 'No (N)'	System	01 Oct 2020 02:31:16

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:05', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '22036cc4-464e-4131-947a-0b6d89dcac2a' User entered 'No (N)'	System	01 Oct 2020 02:31:16
	System	01 Oct 2020 02:31:16

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:11', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '22036cc4-464e-4131-947a-0b6d89dcac2a'	System	01 Oct 2020 02:31:16
User entered 'None (1)'	System	01 Oct 2020 02:31:16

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:13', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '22036cc4-464e-4131-947a-0b6d89dcac2a' User entered '30 Sep 2020 22:31'	System	01 Oct 2020 02:31:16
	System	01 Oct 2020 02:31:16

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 3'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:13', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a5c4b7cb-2e5f-4534-b69b-ee1cd30d535b'	System	02 Oct 2020 02:05:26
User entered 'None (1)'	System	02 Oct 2020 02:05:26

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:15', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a5c4b7cb-2e5f-4534-b69b-ee1cd30d535b'	System	02 Oct 2020 02:05:26
User entered 'No (N)'	System	02 Oct 2020 02:05:26

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:17', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a5c4b7cb-2e5f-4534-b69b-ee1cd30d535b' User entered 'No (N)'	System	02 Oct 2020 02:05:26
	System	02 Oct 2020 02:05:26

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:20', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a5c4b7cb-2e5f-4534-b69b-ee1cd30d535b'	System	02 Oct 2020 02:05:26
User entered 'None (1)'	System	02 Oct 2020 02:05:26

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:22', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a5c4b7cb-2e5f-4534-b69b-ee1cd30d535b' User entered '01 Oct 2020 22:05'	System	02 Oct 2020 02:05:26
	System	02 Oct 2020 02:05:26

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 4'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:05', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7ffbfc3-7ffd-4d3e-bd03-986a388774d0'	System	02 Oct 2020 23:53:19
User entered 'None (1)'	System	02 Oct 2020 23:53:19

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:08', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7ffbfc3-7ffd-4d3e-bd03-986a388774d0'	System	02 Oct 2020 23:53:19
User entered 'No (N)'	System	02 Oct 2020 23:53:19

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:10', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7ffbfc3-7ffd-4d3e-bd03-986a388774d0'	System	02 Oct 2020 23:53:19
User entered 'No (N)'	System	02 Oct 2020 23:53:19

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7ffbfc3-7ffd-4d3e-bd03-986a388774d0'	System	02 Oct 2020 23:53:19
User entered 'None (1)'	System	02 Oct 2020 23:53:19

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:16', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '7ffbfc3-7ffd-4d3e-bd03-986a388774d0' User entered '02 Oct 2020 19:53'	System	02 Oct 2020 23:53:19
	System	02 Oct 2020 23:53:19

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 5'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 6'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:19', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd008c2ac-f81f-437f-9f74-70f92d3979db'	System	05 Oct 2020 02:36:28
User entered 'None (1)'	System	05 Oct 2020 02:36:28

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:21', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd008c2ac-f81f-437f-9f74-70f92d3979db' User entered 'No (N)'	System	05 Oct 2020 02:36:28
	System	05 Oct 2020 02:36:28

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:22', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd008c2ac-f81f-437f-9f74-70f92d3979db'	System	05 Oct 2020 02:36:28
User entered 'No (N)'	System	05 Oct 2020 02:36:28

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:24', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd008c2ac-f81f-437f-9f74-70f92d3979db'	System	05 Oct 2020 02:36:28
User entered 'None (1)'	System	05 Oct 2020 02:36:28

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:26', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd008c2ac-f81f-437f-9f74-70f92d3979db' User entered '04 Oct 2020 22:36'	System	05 Oct 2020 02:36:28
	System	05 Oct 2020 02:36:28

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 7'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:21', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd3d60e4d-bda5-4e91-8d5c-47f775d4f186'	System	06 Oct 2020 04:00:32
User entered 'None (1)'	System	06 Oct 2020 04:00:32

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:24', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd3d60e4d-bda5-4e91-8d5c-47f775d4f186'	System	06 Oct 2020 04:00:32
User entered 'No (N)'	System	06 Oct 2020 04:00:32

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:26', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd3d60e4d-bda5-4e91-8d5c-47f775d4f186' User entered 'No (N)'	System	06 Oct 2020 04:00:32
	System	06 Oct 2020 04:00:32

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:28', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd3d60e4d-bda5-4e91-8d5c-47f775d4f186'	System	06 Oct 2020 04:00:32
User entered 'None (1)'	System	06 Oct 2020 04:00:32

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:30', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'd3d60e4d-bda5-4e91-8d5c-47f775d4f186' User entered '06 Oct 2020 00:00'	System	06 Oct 2020 04:00:32
	System	06 Oct 2020 04:00:32

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:20', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:25', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:28', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:30', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:32', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:33', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'None (0)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:37', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662'	System	29 Sep 2020 16:07:41
User entered 'No (N)'	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T12:07:40', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '70856332-62e4-42ca-b6e3-4b93794c1662' User entered '29 Sep 2020 12:07'	System	29 Sep 2020 16:07:41
	System	29 Sep 2020 16:07:41

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 11:54'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 14:24'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:41', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'No interference with activity (1)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:47', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'No interference with activity (1)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:52', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'No interference with activity (1)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:02:57', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'None (0)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:03:04', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'None (0)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:03:07', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'None (0)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:03:11', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered 'No (N)'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-29T20:03:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'b5e6cb6f-e0f2-485d-8406-37c3f693e592'	System	30 Sep 2020 00:03:15
User entered '29 Sep 2020 20:03'	System	30 Sep 2020 00:03:15

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '29 Sep 2020 15:19'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 2'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:17', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0'	System	01 Oct 2020 02:31:35
User entered 'None (0)'	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:19', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0' User entered 'None (0)'	System	01 Oct 2020 02:31:35
	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:23', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0' User entered 'None (0)'	System	01 Oct 2020 02:31:35
	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:24', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0' User entered 'None (0)'	System	01 Oct 2020 02:31:35
	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:26', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0'	System	01 Oct 2020 02:31:35
User entered 'None (0)'	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:27', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0'	System	01 Oct 2020 02:31:35
User entered 'None (0)'	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:29', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0' User entered 'No (N)'	System	01 Oct 2020 02:31:35
	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-09-30T22:31:31', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'f73345a3-de9b-4543-8065-ea60259990a0'	System	01 Oct 2020 02:31:35
User entered '30 Sep 2020 22:31'	System	01 Oct 2020 02:31:35

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 3'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:34', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60'	System	02 Oct 2020 02:05:52
User entered 'No interference with activity (1)'	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:37', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60' User entered 'None (0)'	System	02 Oct 2020 02:05:52
	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:38', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60' User entered 'None (0)'	System	02 Oct 2020 02:05:52
	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:41', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60' User entered 'None (0)'	System	02 Oct 2020 02:05:52
	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:42', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60'	System	02 Oct 2020 02:05:52
User entered 'None (0)'	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:44', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60' User entered 'None (0)'	System	02 Oct 2020 02:05:52
	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:47', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60'	System	02 Oct 2020 02:05:52
User entered 'No (N)'	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-01T22:05:50', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '89e01dfa-b61c-430a-acb9-17e37e64bd60' User entered '01 Oct 2020 22:05'	System	02 Oct 2020 02:05:52
	System	02 Oct 2020 02:05:52

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 4'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:28', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'No interference with activity (1)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:33', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'None (0)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:35', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'None (0)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:36', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'None (0)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:38', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'None (0)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:40', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'None (0)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:44', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered 'No (N)'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-02T19:53:46', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a989aae7-70b0-4946-b51b-9767362384a5'	System	02 Oct 2020 23:53:48
User entered '02 Oct 2020 19:53'	System	02 Oct 2020 23:53:48

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 5'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 6'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:29', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:30', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:31', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:32', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:33', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:34', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'None (0)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:38', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered 'No (N)'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-04T22:36:39', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e1c26f96-1b3c-46dd-a1a8-1ad2382d7861' User entered '04 Oct 2020 22:36'	System	05 Oct 2020 02:36:42
	System	05 Oct 2020 02:36:42

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
Data entry locked.	System	29 Sep 2020 15:41:00
User entered 'Day 7'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:08', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:09', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:11', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:13', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:14', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'None (0)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

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)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:17', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered 'No (N)'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2020-10-06T00:00:18', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '4048133b-f6ca-4252-92bf-20924914b016' User entered '06 Oct 2020 00:00'	System	06 Oct 2020 04:00:21
	System	06 Oct 2020 04:00:21

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 15:41:00

US3652039

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:17
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 15:41:00

US3652039

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:00:26

US3652039

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '07 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:00:26

US3652039

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Oct 2020 03:00:26

US3652039

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:00:26

US3652039

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:00:32

US3652039

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	22 Oct 2020 03:00:32

US3652039

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:02:15

US3652039

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '14 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:02:15

US3652039

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Oct 2020 03:02:15

US3652039

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:02:15

US3652039

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:02:20

US3652039

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	22 Oct 2020 03:02:20

US3652039

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:03:39

US3652039

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '20 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:03:39

US3652039

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Oct 2020 03:03:39

US3652039

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:03:39

US3652039

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 03:03:44

US3652039

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	22 Oct 2020 03:03:44

US3652039

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:08

US3652039

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:08

US3652039

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:08

US3652039

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'VISIT2'	System	01 Dec 2020 02:38:08

US3652039

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:13

US3652039

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	01 Dec 2020 02:38:13

US3652039

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:26

US3652039

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:26

US3652039

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:26

US3652039

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:26

US3652039

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:29

US3652039

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	01 Dec 2020 02:38:29

US3652039

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:35

US3652039

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:35

US3652039

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:35

US3652039

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:38:35

US3652039

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Dec 2020 02:38:40

US3652039

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	01 Dec 2020 02:38:40

US3652039

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Dec 2020 02:39:19

US3652039

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '17 Nov 2020'	Jiamin Li (b) (4)	01 Dec 2020 02:39:19

US3652039

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	01 Dec 2020 02:39:19

US3652039

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	01 Dec 2020 02:39:19

US3652039

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Dec 2020 02:39:24

US3652039

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	01 Dec 2020 02:39:24

US3652039

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	05 Jan 2021 20:44:12

US3652039

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:12

US3652039

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:12

US3652039

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered 'VISIT3'	System	05 Jan 2021 20:44:12

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:17

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59

US3652039

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59

US3652039

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	05 Jan 2021 20:44:26

US3652039

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:26

US3652039

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'No (N)'	Jiamin Li (b) (4)	05 Jan 2021 20:44:30

US3652039

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:30

US3652039

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:44:30

US3652039

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered empty.	System	05 Jan 2021 20:44:30

US3652039

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	05 Jan 2021 20:44:34

US3652039

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	05 Jan 2021 20:44:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-14T15:50:56', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '73997ff7-e5f4-4c4d-b067-6e89487ed72a'	System	14 Jan 2021 20:51:34
User entered 'Yes (Y)'	System	14 Jan 2021 20:51:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-14T15:51:01', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '73997ff7-e5f4-4c4d-b067-6e89487ed72a'	System	14 Jan 2021 20:51:34
User entered 'No (N)'	System	14 Jan 2021 20:51:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-14T15:51:13', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '73997ff7-e5f4-4c4d-b067-6e89487ed72a'	System	14 Jan 2021 20:51:34
User entered 'No (N)'	System	14 Jan 2021 20:51:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-14T15:51:16', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '73997ff7-e5f4-4c4d-b067-6e89487ed72a'	System	14 Jan 2021 20:51:34
User entered 'No (N)'	System	14 Jan 2021 20:51:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-14T15:51:30', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '73997ff7-e5f4-4c4d-b067-6e89487ed72a'	System	14 Jan 2021 20:51:34
User entered '14 Jan 2021 15:51:30'	System	14 Jan 2021 20:51:34

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-25T10:31:20', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '933410fe-f06b-4137-93db-0be684c4d708'	System	25 Jan 2021 15:31:28
User entered 'No (N)'	System	25 Jan 2021 15:31:28

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-25T10:31:22', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '933410fe-f06b-4137-93db-0be684c4d708'	System	25 Jan 2021 15:31:28
User entered 'No (N)'	System	25 Jan 2021 15:31:28

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-25T10:31:25', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '933410fe-f06b-4137-93db-0be684c4d708' User entered '25 Jan 2021 10:31:25'	System	25 Jan 2021 15:31:28
	System	25 Jan 2021 15:31:28

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-31T10:38:10', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'c67bee94-b16f-4270-920b-a6a92ec821cf'	System	31 Jan 2021 15:38:18
User entered 'No (N)'	System	31 Jan 2021 15:38:18

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-31T10:38:12', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'c67bee94-b16f-4270-920b-a6a92ec821cf'	System	31 Jan 2021 15:38:18
User entered 'No (N)'	System	31 Jan 2021 15:38:18

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-01-31T10:38:15', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'c67bee94-b16f-4270-920b-a6a92ec821cf' User entered '31 Jan 2021 10:38:15'	System	31 Jan 2021 15:38:18
	System	31 Jan 2021 15:38:18

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-13T14:54:33', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '58442945-92a3-4673-a257-99cddb79ed93'	System	13 Feb 2021 19:54:41
User entered 'No (N)'	System	13 Feb 2021 19:54:41

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-13T14:54:35', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '58442945-92a3-4673-a257-99cddb79ed93'	System	13 Feb 2021 19:54:41
User entered 'No (N)'	System	13 Feb 2021 19:54:41

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-13T14:54:38', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '58442945-92a3-4673-a257-99cddb79ed93'	System	13 Feb 2021 19:54:41
User entered '13 Feb 2021 14:54:38'	System	13 Feb 2021 19:54:41

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-20T10:06:26', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '92a8472f-64e5-4150-a4fc-e76c836d2722'	System	20 Feb 2021 15:06:38
User entered 'No (N)'	System	20 Feb 2021 15:06:38

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-20T10:06:29', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '92a8472f-64e5-4150-a4fc-e76c836d2722'	System	20 Feb 2021 15:06:38
User entered 'No (N)'	System	20 Feb 2021 15:06:38

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-20T10:06:31', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '92a8472f-64e5-4150-a4fc-e76c836d2722' User entered '20 Feb 2021 10:06:31'	System	20 Feb 2021 15:06:38
	System	20 Feb 2021 15:06:38

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-27T10:02:56-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '9ed97ad2-de84-4fe0-a0d1-9db87a5d5a8d'	System	27 Feb 2021 15:03:07
User entered 'No (N)'	System	27 Feb 2021 15:03:07

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-27T10:02:58-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '9ed97ad2-de84-4fe0-a0d1-9db87a5d5a8d'	System	27 Feb 2021 15:03:07
User entered 'No (N)'	System	27 Feb 2021 15:03:07

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-02-27T10:03:00-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '9ed97ad2-de84-4fe0-a0d1-9db87a5d5a8d'	System	27 Feb 2021 15:03:07
User entered '27 Feb 2021 15:03:00'	System	27 Feb 2021 15:03:07

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-08T11:50:25-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '633c2fbf-2dc0-494a-aaec-b51f45ce0c2a'	System	08 Mar 2021 16:50:37
User entered 'No (N)'	System	08 Mar 2021 16:50:37

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-08T11:50:28-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '633c2fbf-2dc0-494a-aaec-b51f45ce0c2a'	System	08 Mar 2021 16:50:37
User entered 'No (N)'	System	08 Mar 2021 16:50:37

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-08T11:50:30-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '633c2fbf-2dc0-494a-aaec-b51f45ce0c2a'	System	08 Mar 2021 16:50:37
User entered '08 Mar 2021 11:50:30'	System	08 Mar 2021 16:50:37

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-12T09:06:23-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '51e0e2aa-a467-4c40-9006-a69facafc957'	System	12 Mar 2021 14:06:29
User entered 'No (N)'	System	12 Mar 2021 14:06:29

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-12T09:06:24-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '51e0e2aa-a467-4c40-9006-a69facafc957'	System	12 Mar 2021 14:06:29
User entered 'No (N)'	System	12 Mar 2021 14:06:29

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-12T09:06:26-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '51e0e2aa-a467-4c40-9006-a69facafc957'	System	12 Mar 2021 14:06:29
User entered '12 Mar 2021 09:06:26'	System	12 Mar 2021 14:06:29

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-19T09:51:41-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e73d1e8d-9cbe-4532-823c-03f15f328086'	System	19 Apr 2021 13:51:52
User entered 'No (N)'	System	19 Apr 2021 13:51:52

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-19T09:51:43-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e73d1e8d-9cbe-4532-823c-03f15f328086'	System	19 Apr 2021 13:51:52
User entered 'No (N)'	System	19 Apr 2021 13:51:52

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-19T09:51:46-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'e73d1e8d-9cbe-4532-823c-03f15f328086'	System	19 Apr 2021 13:51:52
User entered '19 Apr 2021 09:51:46'	System	19 Apr 2021 13:51:52

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-22T22:24:26-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '527b6a2d-ef12-4ef1-a23b-0e9ea115f7dd'	System	23 Apr 2021 02:24:35
User entered 'No (N)'	System	23 Apr 2021 02:24:35

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

Have you been exposed to someone with 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 (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-22T22:24:28-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '527b6a2d-ef12-4ef1-a23b-0e9ea115f7dd'	System	23 Apr 2021 02:24:35
User entered 'No (N)'	System	23 Apr 2021 02:24:35

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-04-22T22:24:30-04:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: '527b6a2d-ef12-4ef1-a23b-0e9ea115f7dd'	System	23 Apr 2021 02:24:35
User entered '22 Apr 2021 22:24:30'	System	23 Apr 2021 02:24:35

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 10:49:25

US3652039

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:49:25
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 10:49:25

US3652039

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:59:05

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 01:27:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-01T23:04:05-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a6de4fda-feb7-4651-a76c-86b044dfe398'	System	02 Mar 2021 04:04:32
User entered 'No (N)'	System	02 Mar 2021 04:04:32

US3652039

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:59:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:27:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A410BAE8-FA5A-4CAF-A055-15F92264C507)', Time: '2021-03-01T23:04:11-05:00', User OID: 'PatientReportedOutcome (US3652039)', ODM File OID: 'a6de4fda-feb7-4651-a76c-86b044dfe398'	System	02 Mar 2021 04:04:32
User entered '01 Mar 2021 23:04:11'	System	02 Mar 2021 04:04:32

US3652039

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	05 Jan 2021 20:45:25

US3652039

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered '22 Dec 2020'	Jiamin Li (b) (4)	05 Jan 2021 20:45:25

US3652039

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	05 Jan 2021 20:45:25

US3652039

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered empty.	Jiamin Li (b) (4)	05 Jan 2021 20:45:25

US3652039

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	05 Jan 2021 20:45:29

US3652039

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:18:59
User entered '1'	System	05 Jan 2021 20:45:29

US3652039

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
	[REDACTED]	
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:01:47
	(b) (4)	

US3652039

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
	[REDACTED]	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' canceled (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 12:22:03
	[REDACTED]	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:59:07
	[REDACTED]	
User entered '21 Jan 2021'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:01:47

US3652039

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
	[REDACTED]	
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	11 Feb 2021 17:01:47
	(b) (4)	

US3652039

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 17:01:47
	(b) (4)	

US3652039

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:01:55

US3652039

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User entered '1'	System	11 Feb 2021 17:01:55

US3652039

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:32:33

US3652039

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '24 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:32:33

US3652039

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	25 Feb 2021 23:32:33

US3652039

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:32:33

US3652039

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:32:39

US3652039

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User entered '1'	System	25 Feb 2021 23:32:39

US3652039

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:35:18

US3652039

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '26 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:35:18

US3652039

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	31 Mar 2021 19:35:18

US3652039

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	31 Mar 2021 19:35:18

US3652039

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:35:21

US3652039

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:01
User entered '1'	System	31 Mar 2021 19:35:21

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:18
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:58:02

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:18
User entered '13:20'	Jiamin Li (b) (4)	02 Nov 2020 17:58:02

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:11
User entered '27 Oct 2020 13:20'	System	02 Nov 2020 17:58:02

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:18
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jiamin Li (b) (4)	02 Nov 2020 17:58:02

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 23:56:18
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:58:02

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 1 (Day 1)'	Jiamin Li (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99.3' F	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:02:34

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '28 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '37' C	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	[REDACTED] (b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED] (b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) [REDACTED] (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:10:39

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '29 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '36.4' C	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	[REDACTED]	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	[REDACTED]	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:13:32

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 4 (Day 4)'	Jiamin Li (b) (4)	02 Nov 2020 18:21:58

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '30 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '100'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '36.7' C	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:21:58

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 5 (Day 5)'	Jiamin Li (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '31 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '97.7' F	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:09:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:52:13
User entered 'Day 6 (Day 6)'	Jiamin Li (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '01 Nov 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98.3' F	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:10:50

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 1 (Day 1)'	Jiamin Li (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '25 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per CDM: Assessment Not Done is checked for days 1 and 2, yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:22:16
Query 'Per CDM: Assessment Not Done is checked for days 1 and 2, yet data is present. Please review and reconcile.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:34:43
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:39
User opened query 'Per CDM: Assessment Not Done is checked for days 1 and 2, yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 16:48:13
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:35:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:39
User closed query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:56:19
Query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:35:30
User opened query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:17:07
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Feb 2021 16:34:39
User entered empty.	System	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:39
DataPoint Un-verified.	(b) (4)	(b) (4)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:54:29
	(b) (4)	

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:54:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '26 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:56
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:35:41
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:56
User closed query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:57:46
Query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:35:45
User opened query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:17:26
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:55:29

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Feb 2021 16:34:56
User entered empty.	System	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:34:56
DataPoint Un-verified.	(b) (4)	(b) (4)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:55:29
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:55:29

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 11 (Day 11)'	Jiamin Li (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '04 Nov 2020'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98.2' F reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:55:53
User entered '98.2' C	Jiamin Li (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 22:10:17

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 9 (Day 9)'	Jiamin Li (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '02 Nov 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '96.5' F	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:37:04

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 12 (Day 12)'	Jiamin Li (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '05 Nov 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98.2' F	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:01:31

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 14 (Day 14)'	Jiamin Li (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '07 Nov 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98.2' F	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:14:16

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 15 (Day 15)'	Jiamin Li (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '08 Nov 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '99'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '97.1' F	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:15:12

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 16 (Day 16)'	Jiamin Li (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '09 Nov 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '98'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered '97.5' F	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:43:49
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:16:28

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Day 28 (Day 28)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '01 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '98'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
User entered '%'	System	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '97.8' F	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:59:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:30
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'None (None)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:07

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[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 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

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 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
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)	09 Nov 2020 05:46:27
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).	Jiamin Li (b) (4)	02 Nov 2020 22:11:27
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 Nov 2020 22:11:23
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	02 Nov 2020 22:11:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 22:11:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Nov 2020 18:03:15
	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[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 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:49
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:03:15

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:05

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:35
User entered '1'	System	02 Nov 2020 22:11:23

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[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 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

US3652039

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:59:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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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 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
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[Evidence of Shock Requires Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
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User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
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User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
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User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:47:57
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:56:09

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:59:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:15:55
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:48:03
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 17:37:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 16:15:56
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 18:23:38

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm the correct date 29OCT2020 or 30OCT2020 for DAY 3 visit. If 29OCT2020 is confirmed please consider to update the sample details for Day 3 in EDC. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:06:44
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm the correct date 29OCT2020 or 30OCT2020 for DAY 3 visit. If 29OCT2020 is confirmed please consider to update the sample details for Day 3 in EDC. Thank you. ' answered with 'Confirmed day 3 is 29OCT2020, but sample was collected on day 4 (30oct2020)' (Site from DM).	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:36:56
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm the correct date 29OCT2020 or 30OCT2020 for DAY 3 visit. If 29OCT2020 is confirmed please consider to update the sample details for Day 3 in EDC. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:48:31
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample 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)	18 Dec 2020 04:48:31
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample 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 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 20:07:50

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample 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). User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6) [REDACTED] Jiamin Li (b) (4) [REDACTED]	04 Dec 2020 08:29:39 03 Nov 2020 15:58:54

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:59:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:58:54

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	17 Dec 2020 20:07:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 12:35:09
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:33:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:47:11
User entered '29 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:58:54

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 16NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:15:11
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 and 16NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:47:42
User accepted default value 'Day 5 (Day 5)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:59:29

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:59:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:56:06
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	19 Nov 2020 18:35:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:47:23
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:59:29

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per GCL Lab Recon: Re-query: Saliva: Thanks for the response, however Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:06:10
Query 'Per GCL Lab Recon: Re-query: Saliva: Thanks for the response, however Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Confirmed day 5 is 30OCT2020, but sample was collected on day 6 (31oct2020)' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:37:18
User opened query 'Per GCL Lab Recon: Re-query: Saliva: Thanks for the response, however Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:46:16
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:46:16
Query 'Per GCL Lab Recon: Saliva: Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	17 Dec 2020 20:07:41

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 31OCT2020 for Day 5 is recorded in EDC, however sample is reported with 30OCT2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:19:06
User entered '31 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:33:38
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	19 Nov 2020 18:35:17
User entered '31 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:59:29

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User accepted default value 'Day 7 (Day 7)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:27:16

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:59:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Nov 2020 21:27:16

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '02 Nov 2020'	Jiamin Li (b) (4)	11 Nov 2020 21:27:16

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User accepted default value 'Day 9 (Day 9)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:27:24

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:59:05

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per source saliva sample was collected. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:34:16
Query 'Per source saliva sample was collected. Please confirm/correct. ' answered with 'Corrected' (Site from CRA).	Jiamin Li (b) (4)	14 Nov 2020 02:18:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	14 Nov 2020 02:18:34
User opened query 'Per source saliva sample was collected. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:13:07
User entered 'NA (COVID-19 Negative) (NA)'	Jiamin Li (b) (4)	11 Nov 2020 21:27:24

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '04 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	14 Nov 2020 02:18:34
User entered empty.	Jiamin Li (b) (4)	11 Nov 2020 21:27:24

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User accepted default value 'Day 14 (Day 14)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:27:39

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:59:05

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per source saliva sample was collected. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 02:34:25
Query 'Per source saliva sample was collected. Please confirm/correct. ' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	14 Nov 2020 02:19:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	14 Nov 2020 02:19:14
User opened query 'Per source saliva sample was collected. Please confirm/correct. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:13:20
User entered 'NA (COVID-19 Negative) (NA)'	Jiamin Li (b) (4)	11 Nov 2020 21:27:39

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '09 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	14 Nov 2020 02:19:14
User entered empty.	Jiamin Li (b) (4)	11 Nov 2020 21:27:39

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User accepted default value 'Day 21 (Day 21)'	Jiamin Li (b) (4) (b) (4)	07 Dec 2020 16:33:23

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:59:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	07 Dec 2020 16:33:23

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '16 Nov 2020'	Jiamin Li (b) (4)	07 Dec 2020 16:33:23

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
User accepted default value 'Day 28 (Day 28)'	Jiamin Li (b) (4) (b) (4)	07 Dec 2020 16:32:34

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	07 Dec 2020 16:32:34

US3652039

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '01 Dec 2020'	Jiamin Li (b) (4)	07 Dec 2020 16:32:34

US3652039

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:26:59
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:26:59
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 10:25:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:26:59
User entered 'Home (Home)'	Jiamin Li (b) (4)	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:35
User entered 'SICKD1'	System	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:53:46
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:58:01
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:57:54
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User entered empty.	System	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:53:48
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:58:03
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:57:54
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:57:54
DataPoint set to visible.	System	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:53:50
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:58:05
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:57:54
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:57:54
DataPoint set to visible.	System	03 Nov 2020 15:57:21

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered '99.3' F	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered 'Other (Other)'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered 'Information not specified.'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered '80'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User entered 'bpm'	System	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:54:05
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:58:07
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:57:54
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User entered empty.	System	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered '104'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User entered 'mmHg'	System	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:39
User entered '72'	Jiamin Li (b) (4)	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28
User entered 'mmHg'	System	03 Nov 2020 15:57:54

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28

US3652039

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:28

US3652039

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:21
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:45
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:58:12

US3652039

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:21
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:27:45
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:58:12

US3652039

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:05

[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 10:24:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:28:11
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:58:28

US3652039

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:24:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:28:11
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:58:28

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported in Convalescence Visit Day 28 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)	12 Feb 2021 08:27:00
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported in Convalescence Visit Day 28 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 'Information already recorded' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:34:18
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported in Convalescence Visit Day 28 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)	10 Dec 2020 08:31:37
User entered 'Yes (Y)'	Ashley Machado (b) (4)	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '01 Dec 2020'	Ashley Machado (b) (4)	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4)	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'SICKD28'	System	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '01 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '14:28'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered '01 Dec 2020 14:28'	System	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '166.2' cm	Jiamin Li (b) (4)	17 Dec 2020 20:02:51
DataPoint set to visible.	(b) (4) System	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '72.1' kg	Jiamin Li (b) (4)	17 Dec 2020 20:02:51
DataPoint set to visible.	(b) (4) System	01 Dec 2020 19:31:20

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '36.6' C	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '85'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'bpm'	System	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '16'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'breaths/min'	System	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '145'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'mmHg'	System	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '84'	Jiamin Li (b) (4)	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'mmHg'	System	17 Dec 2020 20:02:51

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 20:01:08

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '01 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 20:01:08

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:05

[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 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 20:05:06

US3652039

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:44:35
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '01 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 20:05:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 13JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Central Laboratory – Nasopharyngeal Swab (Single) form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:32:24
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:32:22
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 13JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Central Laboratory – Nasopharyngeal Swab (Single) form within this folder. Please clarify and update as appropriate.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:37:37
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:37:33
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 13JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded on the Central Laboratory – Nasopharyngeal Swab (Single) form within this folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 21:20:43

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded on the Immunogenicity Assessment form within this folder. Please clarify and update as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 17:18:48
	Ashley Machado (b) (4)	13 Jan 2021 16:25:39
	(b) (4)	

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Ashley Machado (b) (4)	13 Jan 2021 16:25:39

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4)	13 Jan 2021 16:25:39

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 16:25:39

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[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 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:59:46

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:59:46

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Placebo (Placebo)'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:36:00
User entered 'Placebo (Placebo)'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03
	(b) (4)	

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:36:00
User entered 'Placebo (Placebo)'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03
	(b) (4)	

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Ashley Machado (b) (4)	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '1'	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '1'	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '166' cm	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '72.1' kg	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '26.16490'	System	11 Feb 2021 16:45:31
DataPoint set to visible.	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '166' cm	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '72.1' kg	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '26.16490'	System	11 Feb 2021 16:45:31
DataPoint set to visible.	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10:15'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '13 Jan 2021 10:15'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '36.7' C	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '66'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'bpm'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '17'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'breaths/min'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '126'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'mmHg'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '84'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'mmHg'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '166' cm	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '72.1' kg	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '26.16490'	System	11 Feb 2021 16:45:31
DataPoint set to visible.	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '12:36'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '13 Jan 2021 12:36'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '36.8' C	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '71'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'bpm'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '16'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'breaths/min'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '117'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'mmHg'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '74'	Jiamin Li (b) (4)	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'mmHg'	System	11 Feb 2021 16:45:31

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:45:38

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:45:38

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Yes (Y)'	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

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 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'mRNA-1273'	System	13 Jan 2021 16:30:06
DataPoint set to visible.	System	13 Jan 2021 16:26:03

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Per CDA, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 21JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:15:27
Query 'Per CDA, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 21JAN2021. Please review and reconcile.' answered with 'Confirmed correct date is 13JAN2021. A DCF has been submitted to iRT.' (Site from DM).	Jiamin Li (b) (4)	26 Apr 2021 01:34:05
User opened query 'Per CDA, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 21JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:43:16
User entered '13 Jan 2021'	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '11:03'	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '13 Jan 2021 11:03'	System	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Left Arm (LEFT ARM)'	Ashley Machado (b) (4)	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'ONCE'	System	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 16:30:06

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:48:35

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:48:35

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10:40'	Jiamin Li (b) (4)	11 Feb 2021 16:48:35

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '13 Jan 2021 10:40'	System	11 Feb 2021 16:48:35

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:46:16

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:46:16

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10:44'	Jiamin Li (b) (4)	11 Feb 2021 16:46:16

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '13 Jan 2021 10:44'	System	11 Feb 2021 16:46:16

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Ashley Machado (b) (4)	13 Jan 2021 16:30:23

US3652039

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:46:51
User entered '1'	System	13 Jan 2021 16:30:23

US3652039

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:01:34

US3652039

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '22 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 17:01:34

US3652039

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	11 Feb 2021 17:01:34

US3652039

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 17:01:34

US3652039

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	10 Feb 2021 15:53:46

US3652039

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User entered '1'	System	10 Feb 2021 15:53:46

US3652039

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:47
User entered '1'	System	10 Feb 2021 15:53:46
DataPoint set to visible.	System	10 Feb 2021 15:53:46

US3652039

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:11

US3652039

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10 Feb 2021'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:11

US3652039

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Clinic (Clinic)'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:11

US3652039

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'OLD29'	System	10 Feb 2021 15:54:11

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10 Feb 2021'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10:38'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered '10 Feb 2021 10:38'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '36.4' C	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Other (Other)'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Temporal'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '72'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'bpm'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '16'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'breaths/min'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '128'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'mmHg'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '79'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'mmHg'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10 Feb 2021'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '11:20'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered '10 Feb 2021 11:20'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '37.0' C	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '64'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'bpm'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '14'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'breaths/min'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '123'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'mmHg'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '83'	Jiamin Li (b) (4)	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'mmHg'	System	11 Feb 2021 17:19:51

US3652039

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 17:02:56

US3652039

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10 Feb 2021'	Jiamin Li (b) (4)	11 Feb 2021 17:02:56

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

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 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'mRNA-1273'	System	10 Feb 2021 15:54:02
DataPoint set to visible.	System	10 Feb 2021 15:53:46

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10 Feb 2021'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '10:49'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered '10 Feb 2021 10:49'	System	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Left Arm (LEFT ARM)'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'ONCE'	System	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 15:54:02

US3652039

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Sarah Galloway (b) (4)	10 Feb 2021 15:54:17

US3652039

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:25:42
User entered '1'	System	10 Feb 2021 15:54:17

US3652039

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:39

US3652039

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '17 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:31:39

US3652039

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:39

US3652039

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:31:39

US3652039

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:43

US3652039

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:37:26
User entered '1'	System	25 Feb 2021 23:31:43

US3652039

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:23:20

US3652039

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '18 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:23:20

US3652039

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[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 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	31 Mar 2021 19:23:20

US3652039

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered 'OLD57'	System	31 Mar 2021 19:23:20

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '18 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '11:35'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered '18 Mar 2021 11:35'	System	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '36.6' C	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Other (Other)'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Temporal'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '77'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered 'bpm'	System	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '16'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered 'breaths/min'	System	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '113'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered 'mmHg'	System	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '76'	Jiamin Li (b) (4)	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered 'mmHg'	System	31 Mar 2021 19:34:43

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46

US3652039

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46

US3652039

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:30:22

US3652039

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '18 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:30:22

US3652039

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:30:04

US3652039

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '18 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:30:04

US3652039

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '11:49'	Jiamin Li (b) (4)	31 Mar 2021 19:30:04

US3652039

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:02:46
User entered '18 Mar 2021 11:49'	System	31 Mar 2021 19:30:04

US3652039

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:59:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:41:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:08
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:58:39

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 04:15:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 04:15:08
Data point term sent to Coder	System	22 Oct 2020 03:04:45
User entered 'Headache'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '16 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User entered empty.	System	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '16 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User entered empty.	System	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'None (NONE)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
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), (b) (6)	12 Nov 2020 16:22:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
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).	Jiamin Li (b) (4)	11 Nov 2020 18:09:37
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:09:30
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).	(b) (4), (b) (6)	06 Nov 2020 13:22:35
User entered '1'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:09:30
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User entered '0'	System	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40
User entered '0'	System	22 Oct 2020 03:04:38

US3652039

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:48:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:28
User entered	System	04 Nov 2020 15:44:22
'USA-US132-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:44:22
	[REDACTED]	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
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)	03 Nov 2020 18:06:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 18:06:22
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 17:20:46
User entered 'COVID-19 (SARS-CoV-2 Confirmed 10/27/2020)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	(b) (4), (b) (6)	12 Nov 2020 16:22:53
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). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
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).	Jiamin Li (b) (4)	11 Nov 2020 20:24:07
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:24:01
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)	06 Nov 2020 13:21:19
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '25 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:20:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 20:57:31
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:57:31
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 20:56:11
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	(b) (4), (b) (6)	12 Nov 2020 17:37:07
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). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
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.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	11 Nov 2020 20:56:16
User entered '03 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:56:11
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)	10 Nov 2020 18:51:35
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 17:20:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'No (N)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 05:27:47
User closed query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:11:57
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'It is recorded as AE.' (Site from System).	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:36:46
Query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:36:27
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	25 Nov 2020 16:55:54
User opened query 'Per CDM: Please consider to complete 'Dosing Discontinuation' page appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:58:00
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:37:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 20:59:08
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 20:57:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 20:56:19
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:50:58
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 17:20:10

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '1'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered '0'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'PV Query: Please provide the final event outcome, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:37:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
Query 'PV Query: Please provide the final event outcome, when available (when symptoms resolved).' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	11 Nov 2020 20:56:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jiamin Li (b) (4)	11 Nov 2020 20:56:11
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available (when symptoms resolved).' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:00:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
	[REDACTED]	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 17:20:10
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	(b) (4), (b) (6)	27 Apr 2021 15:55:27
DataPoint Verified.	Jiamin Li (b) (4)	19 Nov 2020 16:32:37
DataPoint Un-verified.	(b) (4)	
User entered 'Participant is a 33yr old male enrolled on 9/29/2020. He had no significant medical history and reported himself as at risk of COVID from his spouse's work with COVID+ patients as well as living in housing with >5 people. He received his first injection on 9/29/2020. His second injection was scheduled for 10/27/2020. However, on 10/26/2020 the participant reached out to study to report COVID-like symptoms post a known exposure. He reported that the family's nanny tested positive for COVID on 10/21/2020 and the pt's 8 month old daughter tested positive on 10/22/2020. Pt was asymptomatic at that time and tested negative via a rapid test and a PCR on 10/23/2020 at local urgent care. On 10/25/2020, his wife tested positive. Participant was seen on 10/27/2020 by the study clinicians. At the time of the visit he reported fatigue, body aches, muscle aches, cough, chills, and shortness of breath all mild to moderate. His vitals were stable: T: 99.3, 104/72, HR 80, O2 sat 100%. He was retested by Viracor PCR (positive report 10/31/2020). No medical intervention for his symptoms was required at this visit or thereafter. He did take advil and tylenol for his symptoms. Pt was monitored via televisits for the next 14 days. During this time his O2 sats remained at 99%, his temperature remained normal and he required no medical intervention. He did additionally report sore throat. He reported symptom resolution by 11/5/2020. Saliva was collected per protocol on Day 3, 5, 7, 9, 14, and 21. Saliva Day 3 and 5 returned detected. Saliva Day 7 and 9 reported as snot detected. Saliva day 14 and 21 have not resulted. A 28 day convalescent visit is scheduled for 11/24/2020.' reason for change: Data Entry Error	Jiamin Li (b) (4)	19 Nov 2020 16:32:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:38:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 17:20:10

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 17:20:10

US3652039

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:20:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Lip swelling, LLT: Lip swelling - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 13:27:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 13:27:59
Data point term sent to Coder	System	11 Feb 2021 16:47:53
User entered 'Lower lip swelling'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:47:44
User entered '11:20' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:47:44
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:47:10
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User entered '13 Jan 2021 11:20'	System	11 Feb 2021 16:47:44
User entered empty.	System	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 17:06:30
User entered 'Yes (Y)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
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	11 Feb 2021 17:06:43
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	11 Feb 2021 17:06:43
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	11 Feb 2021 17:06:30
User entered '13 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 17:06:30
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 15:57:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:37:47
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:37:45
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 17:06:38
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 17:06:30
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User entered empty.	System	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Feb 2021 16:47:49
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:47:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Feb 2021 16:47:28
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:47:28
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 17:06:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User entered '0'	System	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16
User entered '0'	System	11 Feb 2021 16:47:10

US3652039

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:16

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:15:45
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Does not meet criteria for an illness visit per clinician' (Site from DM).	Jiamin Li (b) (4)	26 Apr 2021 01:18:14
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:23:06
User coded data point as SOC: General disorders and administration site conditions, HLG: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 20:52:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 20:52:56
Data point term sent to Coder	System	11 Feb 2021 16:50:56
User entered 'Fever (post OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:42:34
Query 'Re-query:Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you ' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:28:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:38:24
User opened query 'Re-query:Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:38:19
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:50:25
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:50:15
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User entered empty.	System	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:42:36
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' answered with 'Participant could not recall estimated stop time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:28:34
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:38:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:38:26
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:50:30
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:50:15
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User entered empty.	System	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User entered '0'	System	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20
User entered '0'	System	11 Feb 2021 16:50:15

US3652039

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:59:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:20

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	13 Feb 2021 17:34:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Feb 2021 17:34:46
Data point term sent to Coder	System	11 Feb 2021 16:51:57
User entered 'Chills (POST OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:51:18
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:28:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:39:09
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:39:07
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:51:32
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:51:26
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User entered empty.	System	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:51:20
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' answered with 'Participant could not recall estimated stop time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:28:47
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for stop date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:39:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:39:11
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:51:38
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:51:26
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User entered empty.	System	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User entered '0'	System	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28
User entered '0'	System	11 Feb 2021 16:51:26

US3652039

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:59:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:16:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 03:07:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 03:07:25
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	26 Apr 2021 01:25:17
Data point term sent to Coder	System	26 Apr 2021 01:24:48
Coding entries removed.	Jiamin Li (b) (4) (b) (4)	26 Apr 2021 01:24:28
User entered 'GENERALIZED MUSCLE ACHE (POST OL AE)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	26 Apr 2021 01:24:28
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:49:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 13:32:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	17 Feb 2021 13:32:03 11 Feb 2021 16:52:58
User entered 'Muscle Ache (Post OL AE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:18
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:28:55
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:39:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:39:24
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:52:27
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:52:21
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User entered empty.	System	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:39:30
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:52:30
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:52:21
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User entered empty.	System	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User entered '0'	System	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53
User entered '0'	System	11 Feb 2021 16:52:21

US3652039

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:51:53

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:06:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:06:56
Data point term sent to Coder	System	11 Feb 2021 16:53:59
User entered 'Fatigue (Post OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:29
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:29:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:40:29
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:40:25
Query 'Data is required. Please provide.' answered with 'Updated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:53:15
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:53:09
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User entered empty.	System	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:40:10
Query 'Data is required. Please provide.' answered with 'Updated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:53:09
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User entered empty.	System	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User entered '0'	System	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18
User entered '0'	System	11 Feb 2021 16:53:09

US3652039

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:18

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 20:58:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 20:58:57
Data point term sent to Coder	System	11 Feb 2021 16:54:01
User entered 'Headache (Post OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:35
Query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:29:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 05:44:48
User opened query 'Re-query:Per CDM: Response noted,kindly provide the estimated time if known for start date. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:40:47
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:53:59
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:53:51
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User entered empty.	System	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 09:04:05
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:53:55
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:53:51
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User entered empty.	System	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User entered '0'	System	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48
User entered '0'	System	11 Feb 2021 16:53:51

US3652039

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:59:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:50:48

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:56:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:56:59
Data point term sent to Coder	System	11 Feb 2021 16:55:01
User entered 'Pain at injection site (Left arm, post OL Jiamin Li AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:41
Query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:29:26
User opened query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 09:29:19
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 09:06:58
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:54:34
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:54:31
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User entered empty.	System	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '15 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 09:07:01
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:54:36
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:54:31
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User entered empty.	System	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User entered '0'	System	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59
User entered '0'	System	11 Feb 2021 16:54:31

US3652039

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:52:59

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:16:19
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Does not meet criteria for an illness visit per clinician' (Site from DM).	Jiamin Li (b) (4) (b) (4)	26 Apr 2021 01:29:58
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:24:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:13:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:13:59
Data point term sent to Coder	System	11 Feb 2021 16:56:02
User entered 'Shortness of breath (Post OL AE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:48
Query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' answered with 'Participant could not recall estimated start time.' (Site from DM).	Jiamin Li (b) (4)	25 Feb 2021 23:29:34
User opened query 'Re-query: Per CDM: Response noted, kindly provide the estimated time if known for start date. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 09:26:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Feb 2021 16:13:45
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:55:15
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:55:11
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User entered empty.	System	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '19 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Feb 2021 16:13:42
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	11 Feb 2021 16:55:17
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 16:55:11
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User entered empty.	System	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User entered '0'	System	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31
User entered '0'	System	11 Feb 2021 16:55:11

US3652039

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:59:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:53:31

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 16:56:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 16:56:54
Data point term sent to Coder	System	11 Feb 2021 16:56:02
User entered 'Sore throat'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '15 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User entered empty.	System	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '16 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User entered empty.	System	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User entered '0'	System	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51
User entered '0'	System	11 Feb 2021 16:55:41

US3652039

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:59:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:49:51

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
User coded data point as SOC: Gastrointestinal disorders, HLG: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Lip swelling, LLT: Lip swelling - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:42:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:42:59
	(b) (4)	
Data point term sent to Coder	System	11 Feb 2021 17:05:16
User entered 'Lower lip swelling'	Jiamin Li (b) (4)	11 Feb 2021 17:04:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 17:04:45
	(b) (4)	

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Feb 2021 17:04:59
User entered '10 Feb 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 17:04:59
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Feb 2021 17:04:45
User entered '20 Feb 2021'	Jiamin Li (b) (4)	11 Feb 2021 17:04:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
	[REDACTED]	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 17:05:45
User entered '11:14' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 17:05:45
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 17:04:59
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 17:04:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Feb 2021 11:14'	System	11 Feb 2021 17:05:45
User entered empty.	System	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) [REDACTED]	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 17:04:45

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:16:32
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Does not meet criteria for an illness visit per clinician' (Site from DM).	Jiamin Li (b) (4)	26 Apr 2021 01:31:21
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:24:58
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 23:31:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 23:31:06
Data point term sent to Coder	System	25 Feb 2021 23:30:25
User entered 'Headache'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '10 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '22:00'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User entered '10 Feb 2021 22:00'	System	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '11 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '22:00'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User entered '11 Feb 2021 22:00'	System	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:21

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User entered '0'	System	25 Feb 2021 23:30:21

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14
User entered '0'	System	25 Feb 2021 23:30:21

US3652039

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:14

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 23:32:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 23:32:06
Data point term sent to Coder	System	25 Feb 2021 23:31:26
User entered 'Fatigue'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '10 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '22:00'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User entered '10 Feb 2021 22:00'	System	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '11 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '22:00'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User entered '11 Feb 2021 22:00'	System	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '1'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:32
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User entered '0'	System	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43
User entered '0'	System	25 Feb 2021 23:30:51

US3652039

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 11 Aug 2021 22:59:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:54:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:59:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:36:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 03:50:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:14:37

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 08:16:48
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)	02 Oct 2020 08:16:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 08:16:48
Data point term sent to Coder	System	02 Oct 2020 04:15:13
User entered 'Multivitamin Adult'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Supplement'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	[REDACTED]	
User entered '1'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	[REDACTED]	
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	[REDACTED]	
User entered 'once daily (QD)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	[REDACTED]	
User entered '1'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	[REDACTED]	
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Oct 2020 04:15:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 04:15:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 04:15:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 04:15:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:00:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:00:37
Data point term sent to Coder Coding entries removed.	System Jiamin Li (b) (4)	11 Nov 2020 18:11:32 11 Nov 2020 18:10:40
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:20:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:20:32
Data point term sent to Coder User entered 'Advil'	System Jiamin Li (b) (4) (b) (4)	22 Oct 2020 03:00:45 22 Oct 2020 02:59:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:36:59
Query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' answered with 'Does not meet reporting criteria.' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:36:12
User opened query 'Per CDM Re-Query: Please confirm if this SAR meets any AE reporting criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:25:11
User closed query 'Per DM CLR: Please provide the location/type of pain (eg, pain at injection site, headache etc). Review if condition is present in diary met AE reporting criteria and should be recorded as solicited event in AE ecrf. Else, confirm that this condition did not meet AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:25:11
Query 'Per DM CLR: Please provide the location/type of pain (eg, pain at injection site, headache etc). Review if condition is present in diary met AE reporting criteria and should be recorded as solicited event in AE ecrf. Else, confirm that this condition did not meet AE reporting criteria.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:10:43
User entered 'HEADACHE PAIN (EDIARY SYMPTOMS)' reason for change: Data Entry Error DataPoint Un-verified.	Jiamin Li (b) (4)	11 Nov 2020 18:10:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
User opened query 'Per DM CLR: Please provide the location/type of pain (eg, pain at injection site, headache etc). Review if condition is present in diary met AE reporting criteria and should be recorded as solicited event in AE ecrf. Else, confirm that this condition did not meet AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	(b) (4), (b) (6)	06 Nov 2020 14:08:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain (eDiary symptoms)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:59:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '200'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'mg (mg)'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'twice daily (BID)' reason for change:	Jiamin Li (b) (4)	11 Nov 2020 18:10:40
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'other (OTHER)'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:58:45
Query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:10:47
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:10:40
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User opened query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:15:39
User entered 'Twice'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '01 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '01 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per CDM: Response is NO, however the indication (pain) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' (Site from DM). Query 'Per CDM: Response is NO, however the indication (pain) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 04:59:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:11:14
DataPoint Un-verified.	(b) (4)	11 Nov 2020 18:11:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
User opened query 'Per CDM: Response is NO, however the indication (pain) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 17:45:25
	(b) (4), (b) (6)	06 Nov 2020 09:20:09
	Jiamin Li (b) (4)	22 Oct 2020 02:59:50
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User entered '2'	System	11 Nov 2020 18:10:40
User entered empty.	System	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User entered '1'	System	11 Nov 2020 18:10:40
User entered empty.	System	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:16
User entered '804 (804)'	System	11 Nov 2020 18:10:40
User entered empty.	System	22 Oct 2020 02:59:50

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:16:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:16:07
Data point term sent to Coder	System	22 Oct 2020 03:05:46
User entered 'Advil'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Headache'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '200'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'mg (mg)'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'twice daily (BID)' reason for change:	Jiamin Li (b) (4)	11 Nov 2020 18:11:26
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'other (OTHER)'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:00:02
Query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:11:33
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:11:26
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User opened query 'Per CDM: Please confirm if frequency is "Twice daily" as per drop down list and update accordingly or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:16:39
User entered 'Twice'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '16 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '0'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '16 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:44:55
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:33:01
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:32:56
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 04:14:50
User closed query 'Per CDM: Response is NO, however the indication (Headache) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:00:29
Query 'Per CDM: Response is NO, however the indication (Headache) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:11:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 18:11:30
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response is NO, however the indication (Headache) reflects one of the solicited event for the study. Please consider to update or else clarify. Thank you.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 09:22:21
	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User entered '2'	System	11 Nov 2020 18:11:26
User entered empty.	System	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User entered '1'	System	11 Nov 2020 18:11:26
User entered empty.	System	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:17
User entered '804 (804)'	System	11 Nov 2020 18:11:26
User entered empty.	System	22 Oct 2020 03:05:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:26:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:26:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:15:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:15:36
Data point term sent to Coder Coding entries removed.	System Jiamin Li (b) (4)	11 Nov 2020 18:38:04 11 Nov 2020 18:37:55
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:46:13

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:46:13
Data point term sent to Coder	System	02 Nov 2020 17:52:14
User entered 'Ibuprofen'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'COVID-19 SYMPTOMS' reason for change: Data Entry Error DataPoint Un-verified.	Jiamin Li (b) (4)	11 Nov 2020 18:37:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
User entered 'Presumed COVID-19 symptoms'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '400'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'mg (mg)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'three times daily (TID)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:25:55
Query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' answered with 'CM start date is consistent with COVID-19 diagnosis start date. ' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:37:49
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User opened query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:08:44
User entered '25 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:23:30
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:52:45
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User entered '3'	System	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User entered '1'	System	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:22
User entered '804 (804)'	System	02 Nov 2020 17:52:12

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 18:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 18:55:35
Data point term sent to Coder	System	11 Nov 2020 18:39:06
Coding entries removed.	Jiamin Li (b) (4)	11 Nov 2020 18:38:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 06:09:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 06:09:08
Data point term sent to Coder	System	02 Nov 2020 17:56:18
User entered 'Acetaminophen'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'COVID-19 SYMPTOMS' reason for change: Data Entry Error DataPoint Un-verified.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 18:38:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
User entered 'Presumed COVID-19 Symptoms'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '500'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'mg (mg)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '25 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:27:25
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:23:20
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'COVID-19 symptoms are solicited per protocol.' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:38:45
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:21:43
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User entered '2'	System	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User entered '1'	System	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:24
User entered '804 (804)'	System	02 Nov 2020 17:56:16

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:26:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:15:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:15:37
Data point term sent to Coder Coding entries removed.	System Jiamin Li (b) (4)	11 Nov 2020 18:39:07 11 Nov 2020 18:38:57
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:46:14

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:46:14
Data point term sent to Coder	System	02 Nov 2020 18:15:47
User entered 'Ibuprofen'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'COVID-19 SYMPTOMS' reason for change: Data Entry Error DataPoint Un-verified.	Jiamin Li (b) (4)	11 Nov 2020 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
User entered 'Presumed COVID-19 Symptoms'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '400'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'mg (mg)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'once (ONCE)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '29 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User entered '29 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User closed query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:29:08
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Nov 2020 20:23:12
Query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' answered with 'Consistent with covid-19 time frame, solicited.' (Site from DM).	Jiamin Li (b) (4)	11 Nov 2020 18:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:25
User opened query 'Per DM CLR: Note, was this medication taken for solicited event=Yes. However CM start date is after the solicited event reporting period and is not recorded in Diary. Review if this should be ticked as NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:09:32
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User entered empty.	System	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User entered empty.	System	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:27
User entered empty.	System	02 Nov 2020 18:15:04

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 21:33:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 21:33:36
Data point term sent to Coder Coding entries removed.	System	11 Nov 2020 21:33:00
	Jiamin Li (b) (4)	11 Nov 2020 21:32:49
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 21:26:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 21:26:36
Data point term sent to Coder	System	11 Nov 2020 21:25:50
User entered 'Acetaminophen'	Jiamin Li (b) (4)	11 Nov 2020 21:25:29
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User entered 'COVID-19 SYMPTOMS (sore throat)'	Jiamin Li (b) (4)	11 Nov 2020 21:32:49
reason for change: Data Entry Error	(b) (4)	
User entered 'COVID-19 Symptoms'	Jiamin Li (b) (4)	11 Nov 2020 21:25:29
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '500'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'as needed (PRN)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User entered '28 Oct 2020'	Jiamin Li (b) (4)	11 Nov 2020 21:25:29
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:29

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Jan 2021 20:14:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Jan 2021 20:14:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:14:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:14:37
Data point term sent to Coder	System	11 Nov 2020 21:33:00
Data point term sent to Coder	System	11 Nov 2020 21:25:51
User entered 'Ibuprofen'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User entered 'COVID-19 SYMPTOMS (sore throat)'	Jiamin Li (b) (4)	11 Nov 2020 21:33:00
reason for change: Data Entry Error	(b) (4)	
User entered 'COVID-19 Symptoms'	Jiamin Li (b) (4)	11 Nov 2020 21:25:49
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User entered '200'	Jiamin Li (b) (4)	11 Nov 2020 21:25:49
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User entered 'as needed (PRN)'	Jiamin Li (b) (4)	11 Nov 2020 21:25:49
	(b) (4)	

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '30 Oct 2020'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:25:49

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	[REDACTED]	
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 00:44:49
Data point term sent to Coder	System	16 Dec 2020 00:44:00
User entered 'Finasteride'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) [REDACTED]	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
	(b) (4), (b) (6)	12 Feb 2021 17:44:22
User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Does not meet criteria for adverse event reporting' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:33:33
User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:44:39
User entered 'Hair loss'	Jiamin Li (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '1'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '10 Nov 2020'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Dec 2020 00:43:27

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 00:46:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Dec 2020 00:46:05
Data point term sent to Coder User entered 'Influenza Vaccine'	System Jiamin Li (b) (4)	16 Dec 2020 00:45:03 16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Yes (Y)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Influenza Prophylaxis'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Unknown'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Unknown'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'once (ONCE)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '10 Nov 2020'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '10 Nov 2020'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User entered empty.	System	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User entered empty.	System	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:41
User entered empty.	System	16 Dec 2020 00:44:17

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 22:24:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 22:24:57
Data point term sent to Coder	System	11 Feb 2021 16:57:03
User entered 'Advil'	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Muscle Ache (Post OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '200'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User entered '2'	System	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User entered '1'	System	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:42
User entered '804 (804)'	System	11 Feb 2021 16:56:52

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 16:58:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 16:58:54
Data point term sent to Coder User entered 'Tylenol'	System Jiamin Li (b) (4)	11 Feb 2021 16:58:05 11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Fever (post OL AE)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '500'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '13 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '14 Jan 2021'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User entered '2'	System	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User entered '1'	System	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:47
User entered '804 (804)'	System	11 Feb 2021 16:57:21

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 23:32:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 23:32:06
Data point term sent to Coder User entered 'Tylenol'	System Jiamin Li (b) (4)	25 Feb 2021 23:31:27 25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Headache'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '1000'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'mg (mg)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered empty.	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '10 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '0'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered '11 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4)	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User entered '2'	System	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User entered '1'	System	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:53:49
User entered '804 (804)'	System	25 Feb 2021 23:31:26

US3652039

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:59:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) [REDACTED]	16 Apr 2021 12:59:19
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	24 Mar 2021 16:06:31

US3652039

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:05

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:15:45
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:07:12
User entered '28 Oct 2020'	Jiamin Li (b) (4)	25 Nov 2020 16:55:54

US3652039

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:05

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:15:45
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
Query 'Re-query: PER CDM: Response noted, kindly mention the log line of AE .Thank you' canceled (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 15:55:08
User opened query 'Re-query: PER CDM: Response noted, kindly mention the log line of AE .Thank you' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:35:03
User closed query 'Per CDM: Please consider to select as "Due to SARS-COV-2" from the mentioned drop down list and remove the details from "If reason is AE, SAE, Physician decision, withdrawal of consent by participant, protocol deviation and other specify". Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:35:03
Query 'Per CDM: Please consider to select as "Due to SARS-COV-2" from the mentioned drop down list and remove the details from "If reason is AE, SAE, Physician decision, withdrawal of consent by participant, protocol deviation and other specify". Thank you.' answered with 'Previous instruction for US3652038 to change the primary reason for dosing discontinuation to "AE(specify)". This was originally entered as due to SARS-COV-2. Please provide consistent instruction as to how you would like for the dosing discontinuation form to be entered for COVID-19 events.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:36:12
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:07:12
User opened query 'Per CDM: Please consider to select as "Due to SARS-COV-2" from the mentioned drop down list and remove the details from "If reason is AE, SAE, Physician decision, withdrawal of consent by participant, protocol deviation and other specify". Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:27:11
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:36:54
User entered 'Due to SARS-COV-2 (COVID)'	Jiamin Li (b) (4) (b) (4)	25 Nov 2020 16:55:54

US3652039

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:05

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:15:45
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:07:32
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Mar 2021 20:42:23
DataPoint Un-verified.	Jiamin Li (b) (4)	11 Mar 2021 20:42:18
User entered 'Ae #2' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Mar 2021 20:42:18
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:12:04
Query 'Per CDM: Please remove AE term from specify field and keep only AE log line number. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:12:01
User opened query 'Per CDM: Please remove AE term from specify field and keep only AE log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:32:52
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:07:12
User closed query 'Per CDM: Please record AE record number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:16:00
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	01 Dec 2020 02:37:02
User entered 'SARS-CoV-2 (AE log line #2)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:37:02

US3652039

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:05

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	01 Dec 2020 02:36:54
Query 'Per CDM: Please record AE record number. Thank you. ' answered with 'System query results when I try to enter this field: " Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct. "' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:35:02
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	01 Dec 2020 02:34:59
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:34:59
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	01 Dec 2020 02:34:37
User entered 'AE #2' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:34:37
User opened query 'Per CDM: Please record AE record number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:02:44
User entered empty.	Jiamin Li (b) (4)	25 Nov 2020 16:55:54

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered	[REDACTED]	04 Nov 2020 15:44:22
'USA-US132-2020-MRNA-1273-P301000002'	System	

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Kristen'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Marks'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '525 East 68th Street'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'New York'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'NY'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '10065'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:37:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
User entered 'US'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 17:37:39
User entered '1'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered	[REDACTED]	
'USA-US132-2020-MRNA-1273-P301000002'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Kristen'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Marks'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '525 East 68th Street'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'New York'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'NY'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '10065'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:37:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
User entered 'US'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 17:37:39
User entered '1'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:59:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
	[REDACTED]	
User entered '04/Nov/2020 15:44'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:59:05

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:37:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 15:44:58
	[REDACTED]	

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered	[REDACTED]	
'USA-US132-2020-MRNA-1273-P301000002'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'No (N)'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Kristen'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'Marks'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '525 East 68th Street'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'New York'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered 'NY'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:44:51
User entered '10065'	System	04 Nov 2020 15:44:22

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
	[REDACTED]	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:37:26
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:44:59
User entered 'US'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 17:37:39
User entered '1'	System	04 Nov 2020 15:44:58

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:59:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:36:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '12/Nov/2020 17:37'	System	12 Nov 2020 17:37:39

US3652039

Folder: SAE USA-US132-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:59:05

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)	16 Apr 2021 22:36:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:00:02
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 17:37:39