

US3652038 (Prod: Weill Cornell Medical College)

Generated By: (b) (6)

Generated On: 11 Jun 2021 15:01:14

All time stamps listed in this document are displayed in GMT

US3652038

Form: Participant Creation

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

Generated On: 11 Jun 2021 15:01:14

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Participant ID

US3652038

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

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US3652038

Folder: Screening

Form: Visit Date

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3652038

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

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	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3652038

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3652038

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

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

Generated On: 11 Jun 2021 15:01:14

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 12:59:15

Generated On: 11 Jun 2021 15:01:14

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: Childbearing Potential

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*) 24 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	25 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3652038

Folder: Screening

Form: Risk of Exposure

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

Generated On: 11 Jun 2021 15:01:14

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**Occupational Risk**

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**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 ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

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

What was the participant's randomization number? 115440

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 20:47:11

Generated On: 11 Jun 2021 15:01:14

Height	162.6 cm
Weight	54.9 kg



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

Height	162.6 cm
Weight	54.9 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)	25 SEP 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 08:48
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 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 20:47:11

Generated On: 11 Jun 2021 15:01:14

Height	162.6 cm
Weight	54.9 kg
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:26
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3652038

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:47:10

Generated On: 11 Jun 2021 15:01:14

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

25 SEP 2020

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

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US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	25 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 SEP 2020

What was the treatment time? (00:00-23:59) 9:53 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 9:53

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 20:46:52

Generated On: 11 Jun 2021 15:01:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	25 SEP 2020
Collection time ( <i>00:00-23:59</i> )	09:21 (24 HR)
Collection date and time (derived)	25 SEP 2020 09:21

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:25	25 SEP 2020 09:25
Nasopharyngeal Swab 2	No		

US3652038

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 25 SEP 2020 10:28

PC Open Date & Time 25 SEP 2020 10:13

PC Close Date & Time 25 SEP 2020 12:43

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	25 SEP 2020 19:21
PC Open Date & Time	25 SEP 2020 13:38
PC Close Date & Time	26 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	26 SEP 2020 19:10
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 21:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 22:55

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**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

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:45

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 10:29

PC Open Date & Time

25 SEP 2020 10:13

PC Close Date & Time

25 SEP 2020 12:43

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 19:22

PC Open Date & Time

25 SEP 2020 13:38

PC Close Date & Time

26 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 19:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 21:15

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 22:55

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 21:45

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**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 ☐

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 10:29
PC Open Date & Time	25 SEP 2020 10:13
PC Close Date & Time	25 SEP 2020 12:43

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**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 ☐

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 19:23
PC Open Date & Time	25 SEP 2020 13:38
PC Close Date & Time	26 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:12
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:15
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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 ☒

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 22:55
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:45
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**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 ☐

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

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

Generated On: 11 Jun 2021 15:01:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	



US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

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

Generated On: 11 Jun 2021 15:01:14

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3652038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

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

Generated On: 11 Jun 2021 15:01:14

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.*

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

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

Generated On: 11 Jun 2021 15:01:14

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3652038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

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

Generated On: 11 Jun 2021 15:01:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3652038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:47:11

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

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 \_\_\_\_\_



US3652038

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:51

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

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 \_\_\_\_\_

US3652038

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

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 \_\_\_\_\_

US3652038

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

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

Generated On: 11 Jun 2021 15:01:14

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) \_\_\_\_\_

US3652038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

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

Generated On: 11 Jun 2021 15:01:14

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.*



US3652038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

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

Generated On: 11 Jun 2021 15:01:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3652038

Folder: Visit 3 Day 57 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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29 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 DEC 2020 11:17:51
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 09:46:44
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59
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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 12:33:01
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 11:13:45

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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 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 JAN 2021 13:12:34
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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	25 JAN 2021 16:32:52
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59



US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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31 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 FEB 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 10:31:59

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 14:11:41

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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

03 MAR 2021 08:31:02

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 15:24:13

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 15:31:33

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:55:25

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 10:57:34

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

Date and time of submission

05 APR 2021 12:09:08

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 14:53:13

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 19:27:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 11:37:06

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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 <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"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUL 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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°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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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°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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**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 ☐

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 782

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:01:14

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2022 23:59

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US3652038

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Jun 2021 15:01:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 08:31:33

US3652038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:46:52

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3652038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

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*

US3652038

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments PARTICIPANT DID NOT PICK UP  
AFTER MULTIPLE ATTEMPTS

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3652038

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

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

Generated On: 11 Jun 2021 15:01:14

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

Visit date (dd MMM yyyy)	13 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3652038

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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)	



US3652038

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

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.*

**US3652038**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:01:14**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3652038

Folder: Visit 4 Day 209 (1)

Form: Continuing

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

Generated On: 11 Jun 2021 15:01:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3652038**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:01:14**

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*

**US3652038**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

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	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

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

Generated On: 11 Jun 2021 15:01:14

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"/>

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

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

Generated On: 11 Jun 2021 15:01:14

	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	99 %	
O2 Saturation Units	%	
Temperature	98.3 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 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"/>



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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

Generated On: 11 Jun 2021 15:01:14

	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 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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

Generated On: 11 Jun 2021 15:01:14

	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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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

Generated On: 11 Jun 2021 15:01:14

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

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

Generated On: 11 Jun 2021 15:01:14

	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	36.6 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 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

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

Generated On: 11 Jun 2021 15:01:14

	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	36.7 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 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"/>



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

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

Generated On: 11 Jun 2021 15:01:14

	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	99 %
---------------	------

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

Temperature	36.9 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 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

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

Generated On: 11 Jun 2021 15:01:14

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

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Form: Symptom Log (7)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Form: Symptom Log (7)

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

Generated On: 11 Jun 2021 15:01:14

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

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Form: Symptom Log (7)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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

Generated On: 11 Jun 2021 15:01:14

Symptom Day

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

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Form: Symptom Log (8)

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

Generated On: 11 Jun 2021 15:01:14

	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	97.9 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Form: Symptom Log (8)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

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

Generated On: 11 Jun 2021 15:01:14

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 checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

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

Generated On: 11 Jun 2021 15:01:14

	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	100 %
---------------	-------

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

Temperature	98.8 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"/>

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Form: Symptom Log (9)

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

Generated On: 11 Jun 2021 15:01:14

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

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Form: Symptom Log (9)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

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

Generated On: 11 Jun 2021 15:01:14

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"/>

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Form: Symptom Log (10)

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

Generated On: 11 Jun 2021 15:01:14

	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	98 %	
O2 Saturation Units	%	
Temperature	97.4 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"/>

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Form: Symptom Log (10)

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

Generated On: 11 Jun 2021 15:01:14

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

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

Generated On: 11 Jun 2021 15:01:14

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

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Form: Symptom Log (11)

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

Generated On: 11 Jun 2021 15:01:14

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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

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

Generated On: 11 Jun 2021 15:01:14

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 checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

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

Generated On: 11 Jun 2021 15:01:14

	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	96.8 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

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

Generated On: 11 Jun 2021 15:01:14

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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

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

Generated On: 11 Jun 2021 15:01:14

	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	97.7 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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

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

Generated On: 11 Jun 2021 15:01:14

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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

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

Generated On: 11 Jun 2021 15:01:14

	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	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

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

Generated On: 11 Jun 2021 15:01:14

	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"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

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

Generated On: 11 Jun 2021 15:01:14

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

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Form: Symptom Log (15)

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

Generated On: 11 Jun 2021 15:01:14

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 checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

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

Generated On: 11 Jun 2021 15:01:14

	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	03 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

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

Generated On: 11 Jun 2021 15:01:14

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 checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

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

Generated On: 11 Jun 2021 15:01:14

	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	06 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

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 SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:13

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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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 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	24 NOV 2020

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

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> )	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

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.*

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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 12:59:14

Generated On: 11 Jun 2021 15:01:14

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020



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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 09:35
Height (xxx.x)	162.6 cm
Weight (xxx.x)	56.2 kg
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 NOV 2020

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

US3652038

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 12:59:13

Generated On: 11 Jun 2021 15:01:14

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 NOV 2020

US3652038

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID UNBLND\_DECIDE

US3652038

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

Form: Unblinding

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

Generated On: 11 Jun 2021 15:01:14

Date of updated informed consent ( <i>dd MMM yyyy</i> )	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	05 DEC 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)



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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 21:41:15

Generated On: 11 Jun 2021 15:01:14

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

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)	07 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)	07 OCT 2020
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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

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 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 (2)

Generated On: 11 Jun 2021 15:01:14

AEID	USA-US132-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	25 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)	06 NOV 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

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PARTICIPANT IS A 34 Y.O FEMALE ENROLLED ON 9/25/2020. SHE HAD NO SIGNIFICANT MEDICAL HISTORY AND REPORTED HERSELF AS AT RISK OF COVID FROM HER WORK AND SUBWAY COMMUTE AS A HEALTH CARE PROVIDER. SHE RECEIVED HER FIRST INJECTION ON 9/25/2020. HER SECOND INJECTION WAS SCHEDULED ON 10/27/2020. HOWEVER, ON 10/26/2020, THE PT REACHED OUT TO STUDY TO REPORT COVID-LIKE SYMPTOMS POST A KNOWN EXPOSURE. SHE 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 10/22/2020 AT LOCAL URGENT CARE. ON 10/25/2020, SHE DEVELOPED MILD TO MODERATE DIARRHEA, NAUSEA, AND FATIGUE. SHE REPEATED PCR TESTING ON 10/26/2020 AND TESTED POSITIVE AT MT SINAI. SHE WAS SEEN ON 10/27/2020 BY STUDY CLINICIANS, WHERE

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Folder: Adverse Events

Form: Adverse Events (2)

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SHE CONTINUED TO REPORT  
FATIGUE, NAUSEA, DIARRHEA  
ALL RATED AS MILD TO  
MODERATE. HER VITALS WERE  
STABLE T:98.3, 98/70, HR 74, O2  
SAT 99%. SHE WAS RETESTED  
BY VIRACOR PCR (POSITIVE  
REPORT 10/31/2020). NO  
MEDICAL INTERVENTION FOR  
HER SYMPTOMS WERE  
REQUIRED AT HER VISIT OR  
THEREAFTER. PT WAS  
MONITORED VIA TELEVITISS  
FOR THE NEXT 14 DAYS.  
DURING THIS TIME, HER O2  
STATS REMAINED ABOVE 97%  
AND HER TEMPERATURE  
REMAINED NORMAL AND SHE  
REQUIRED NO MEDICAL  
INTERVENTION. SHE  
REPORTED SYMPTOM  
RESOLUTION BY 10/28/2020.  
SALIVA WAS COLLECTED PER  
PROTOCOL ON DAY 3, 5, 7, 9, 14,  
AND 21. SALIVA DAY 3 AND 7  
RETURNED POSITIVE. SALIVA  
DAYS 5 AND 9 WERE  
REPORTED AS NOT 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)

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AEID	USA-US132-2020-MRNA-1273-P30 1000003
Adverse event	CRYPTOGENIC STROKE (OFFICIAL DIAGNOSIS ON 12/4, SYMPTOMS BEGINNING ON 11/30)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 NOV 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)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	08 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/>

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	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity	False	
Congenital anomaly or birth defect	False	
Other medically important event	True	
Relationship to investigational product	Not Related	<input 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"/>
<hr/>		
Other action taken (check all that apply)		
None	False	
Concomitant Medication	True	
Concomitant Procedure	True	
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

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Folder: Adverse Events

Form: Adverse Events (3)

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PARTICIPANT IN  
COVE MRNA-1273-P301 RECEIV  
ED INJECTION #1  
ON 9/25/20. PRIOR TO  
RECEIVING INJECTION #2 SHE  
DEVELOPED COVID SX.  
TESTED AT OUTSIDE FACILITY  
ON 10/26/20, COVID  
WAS CONFIRMED AS PER  
STUDY PROCEDURE ON  
10/27/20. COVID CLINICAL  
COURSE WAS UNEVENTFUL,  
NOT REQUIRING ER OR MD  
VISIT, SX WERE  
MILD-MODERATE. PATIENT  
WAS SEEN IN ED ON MONDAY  
11/30 AFTER SHE ACUTELY  
DEVELOPED  
NAUSEA/VOMITING AND  
DIFFICULTY WALKING DUE TO  
THE SENSATION OF BEING  
PULLED TO ONE SIDE. SHE  
WAS GIVEN ZOFRAN X 1 DOSE  
IN ED AND WAS SENT HOME  
ON MECLIZINE 25 MG PO  
TWICE DAILY WITH A  
PRESUMED DX OF  
VERTIGO HER  
SYMPTOMS WERE IMPROVING  
BUT SHE CONTINUED TO HAVE  
SOME VERTIGO WITH  
ASSOCIATED HEADACHE AND  
NAUSEA. SHE SAW A  
NEUROLOGIST ON 12/2/20 WHO  
DID BLOODWORK AND HER  
CBC AND CRP LEVELS WERE  
NORMAL. THE WORKING

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Form: Adverse Events (3)

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DIAGNOSIS AT THAT TIME WAS  
VESTIBULAR NEURITIS BUT  
SHE IS SCHEDULED FOR AN  
MRI ON 12/4 TO RULE OUT  
OTHER CONDITIONS. 12/4/20  
MRI: ACUTE LEFT PICA  
TERRITORY INFARCT MASS  
EFFECT ON THE FOURTH  
VENTRICLE MRA  
H/N-UNREMARKABLE 12/4/20:  
PT OBTAINED A SECOND  
OPINION AND WAS ADMITTED  
TO MT SINAI/BROOKLYN TO  
THE NEURO ICU. PT WAS  
UNBLINDED PER PROTOCOL  
AND ANGIOGRAM, LP, TEE  
PERFORMED. ANGIOGRAM:  
QUESTIONABLE FOCAL  
OCCLUSION OF THE PICA JUST  
LEFT OF MIDLINE. LP:  
NEGATIVE. TEE: PFO WITH R TO  
L SHUNTING (CONSULT WITH  
CONGENITAL HEART  
SPECIALIST). US LE  
EXTREMITIES: NEGATIVE.  
HYPERCOAGULABILITY LABS:  
NO SUGGESTION OF CURRENT  
HYPERCOAGULABLE STATE.  
DX: CRYPTOGENIC STROKE:  
"CRYPTOGENIC STROKE WITH  
ECHOCARDIOGRAM RESULTS  
REVIEWED EXTENSIVELY,  
POINTING TO A PROMINENT  
PFO GIVEN TECHNICAL  
LIMITATIONS OF THE TEE.  
GIVEN HER AGE, STROKE THAT  
CANNOT COMPLETELY

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Form: Adverse Events (3)

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EXCLUDE  
PARADOXICAL/EMBOLIC  
ETIOLOGY, AND A PFO WITH  
CONCERNING FEATURES -  
CONSENSUS AGREEMENT  
MADE TO CLOSE PFO. IN  
ADDITION, HER PRIOR COVID  
STATUS INTRODUCES  
POSSIBLE CONCERN FOR A  
TRANSIENT PROTHROMBOTIC  
STATE GIVEN THAT IT WAS  
ONLY 2 MONTHS AGO. " ON  
12/7/20 PT UNDERWENT  
CLOSURE OF PFO AND WAS  
DISCHARGED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
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---

Medically Attended AE Derived (CSA Programming Field Only)	1
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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 12:59:12

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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) 28 Apr 2021 22:28:29

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Name of Medication MULTIPLE VITAMINS - MINERALS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)	UN JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE LEFT  
ARM (EDIARY 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

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	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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 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) 28 Apr 2021 22:28:29

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Name of Medication REGLAN

Prophylaxis Yes ☐  
No ☒

Indication PICA TERRITORY INFARCT  
MASS EFFECT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

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

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Form: Prior/Concomitant Medication and Vaccination (4)

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

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Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication PICA TERRITORY INFARCT  
MASS EFFECT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

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Form: Prior/Concomitant Medication and Vaccination (5)

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

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Name of Medication MECLIZINE

Prophylaxis Yes ☐  
No ☒

Indication PICA TERRITORY INFARCT  
MASS EFFECT

Dose per administration 25

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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Form: Prior/Concomitant Medication and Vaccination (5)

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

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	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

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Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA AND VOMITING  
(RELATED TO CRYPTOGENIC  
STROKE)

Dose per administration 4

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 (6)

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

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	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☒  
No ☐

Indication STROKE PREVENTION

Dose per administration 80

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 (7)

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

Generated On: 11 Jun 2021 15:01:14

	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)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication APIXABAN

Prophylaxis Yes ☒  
No ☐

Indication STROKE PREVENTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication STROKE PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

Generated On: 11 Jun 2021 15:01:14

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

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENTATION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENTATION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

Generated On: 11 Jun 2021 15:01:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication ANESTHESIA FOR PROCEDURE  
RELATED TO CRYPTOGENIC  
STROKE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 11 Jun 2021 15:01:14

	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 checked="" 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)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANESTHESIA FOR PROCEDURE  
RELATED TO CRYPTOGENIC  
STROKE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 11 Jun 2021 15:01:14

	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 checked="" 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)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication ANESTHESIA FOR PROCEDURE  
RELATED TO CRYPTOGENIC  
STROKE

Dose per administration 4

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 (14)

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

Generated On: 11 Jun 2021 15:01:14

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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 checked="" 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)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

Generated On: 11 Jun 2021 15:01:14

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒  
No ☐

Indication ANTIBIOTIC PROPHYLAXIS FOR  
PROCEDURE RELATED TO  
CRYPTOGENIC STROKE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

Generated On: 11 Jun 2021 15:01:14

	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 checked="" 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)	08 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 12:59:13

Generated On: 11 Jun 2021 15:01:14

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

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

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 DEC 2020	MRA HEAD WITHOUT CONTRAST	Adverse Event	
04 DEC 2020	MR BRAIN WITHOUT CONTRAST	Adverse Event	
04 DEC 2020	MRA NECK WITHOUT CONTRAST	Adverse Event	
05 DEC 2020	LUMBAR PUNCTURE	Adverse Event	
05 DEC 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	
06 DEC 2020	DOPPLER ULTRASOUND (LOWER EXTREMITY)	Adverse Event	
07 DEC 2020	CLOSURE OF THE PATENT FORAMEN OVALE	Adverse Event	
02 DEC 2020	BLOODWORK	Adverse Event	
04 DEC 2020	HYPERCOAGULABILITY LABS.	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 12:59:14

Generated On: 11 Jun 2021 15:01:14

Date of dosing discontinuation (dd MMM yyyy) 24 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 15:01:14

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 ☐

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5



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Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:28
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

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	17/NOV/2020 18:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 23:50
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

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	25/NOV/2020 09:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 12:59:15

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	05/DEC/2020 12:32
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.	False

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	05/DEC/2020 19:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	18/DEC/2020 16:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	28/DEC/2020 20:24
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

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	28/JAN/2021 14:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

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

Generated On: 11 Jun 2021 15:01:14

SAEID	USA-US132-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 11:37
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.	True

Audit

US3652038 (Prod: Weill Cornell Medical College)

**US3652038**

**Form: Participant Creation**

**Generated On: 11 Jun 2021 15:01:14**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:40:34
User entered 'US3652038'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 11:34:08

US3652038

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:30:55
User entered 'Yes (Y)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:05

US3652038

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:30:55
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 11:34:09

US3652038

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:30:55
User entered 'Home (Home)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:05



**US3652038**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:01:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered 'SCRN'	System	25 Sep 2020 12:58:05

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 11:34:10

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '34'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

**US3652038**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:01:14**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered 'YEARS'	System	25 Sep 2020 12:58:36

**US3652038**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:01:14**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered '34'	System	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered 'Female (F)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered 'Hispanic or Latino (HISPANIC OR LATINO)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 19:18:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered 'I'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36



US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered empty.	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:01:14

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36



US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered '24 Sep 2020'	Ashley Machado (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered 'Sep 2020'	System	25 Sep 2020 12:58:59

**US3652038**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered '2020'	System	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'Amendment 3 (3)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'Yes (Y)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered empty.	Ashley Machado (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered empty.	Ashley Machado (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'No (N)'	Ashley Machado (b) (4)	25 Sep 2020 12:58:59



US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 11:34:09

US3652038

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:01:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered 'I'	System	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:11
User entered 'Yes (Y)'	Ashley Machado (b) (4)	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 15:01:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User closed query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 04:03:13
Query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' answered with 'Confirm no significant conditions need to be reported.' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:50:09
User opened query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 07:36:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:16
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:49

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54



US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54
DataPoint set to visible.	(b) (4) System	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54
DataPoint set to visible.	(b) (4) System	25 Sep 2020 13:13:16

**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54
DataPoint set to visible.	System	25 Sep 2020 13:13:16

**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54
DataPoint set to visible.	System	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54



**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20



**US3652038**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20

US3652038

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:27
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:59

US3652038

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:27
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:59

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '24 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:18:20



US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 15:01:14

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:31
DataPoint Un-verified.	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
Query 'Per CDM: Please review and confirm if the pregnancy test is performed for screening dated 24SEP2020, Thank you.' canceled (Site from DM).		10 Nov 2020 06:57:05
User opened query 'Per CDM: Please review and confirm if the pregnancy test is performed for screening dated 24SEP2020, Thank you.' (Site from DM).		06 Nov 2020 08:44:06
User closed query 'Per CDM: Please confirm that whether Pregnancy test has performed or not at Screening, as Childbearing potential is marked as "Yes" on childbearing potential form, kindly clarify else update. Thank you.' (Site from DM).		06 Oct 2020 03:36:37
Query 'Per CDM: Please confirm that whether Pregnancy test has performed or not at Screening, as Childbearing potential is marked as "Yes" on childbearing potential form, kindly clarify else update. Thank you.' answered with 'Done at entry' (Site from DM).	Jiamin Li (b) (4)	05 Oct 2020 01:19:11
User opened query 'Per CDM: Please confirm that whether Pregnancy test has performed or not at Screening, as Childbearing potential is marked as "Yes" on childbearing potential form, kindly clarify else update. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:08:28
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:31
DataPoint Un-verified.	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
User entered '25 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:31
DataPoint Un-verified.	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
User entered 'Urine (URINE)' reason for change:	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:31
DataPoint Un-verified.	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Jiamin Li (b) (4)	21 Jan 2021 16:11:31
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User closed query 'Per CDM: Per CCGs Page number 24, 'Yes' or 'No' should be selected for 'Was FSH Sample Collected'. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:36:27
Query 'Per CDM: Per CCGs Page number 24, 'Yes' or 'No' should be selected for 'Was FSH Sample Collected'. Kindly update accordingly.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	05 Oct 2020 01:19:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 01:19:16
User opened query 'Per CDM: Per CCGs Page number 24, 'Yes' or 'No' should be selected for 'Was FSH Sample Collected'. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:08:47
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05



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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:20:05

**US3652038**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User entered empty.	System	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Form: Risk of Exposure

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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[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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08



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[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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

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[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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

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**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:08



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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 19:22:55
User entered '1'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

**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 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 19:22:55
User entered '0'	Jiamin Li (b) (4)	25 Sep 2020 19:19:08

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:01:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:56:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'Takes public transportation frequently'	Jiamin Li (b) (4)	25 Sep 2020 19:22:55
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:19:08
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered 'Yes (Y)'	Ashley Machado (b) (4)	25 Sep 2020 13:13:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered '25 Sep 2020'	Ashley Machado (b) (4)	25 Sep 2020 13:13:44

US3652038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4)	25 Sep 2020 13:13:44

**US3652038**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:01:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'VISIT1'	System	25 Sep 2020 13:13:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered '25 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:14:25

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered '115440'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:14:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Sep 2020 13:14:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:09
DataPoint set to visible.	(b) (4) System	25 Sep 2020 12:58:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4)	25 Sep 2020 19:22:11



US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '08:48'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered '25 Sep 2020 08:48'	System	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '36.3' C	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '84'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'bpm'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '17'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'breaths/min'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '99'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '66'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:01:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '10:26'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered '25 Sep 2020 10:26'	System	25 Sep 2020 19:22:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '36.6' C	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '76'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'bpm'	System	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '17'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'breaths/min'	System	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '102'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'mmHg'	System	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '68'	Jiamin Li (b) (4)	25 Sep 2020 19:22:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:18
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:22:31

US3652038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:18
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:22:31

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Urine (URINE)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:26



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Negative (NEGATIVE)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:23:26

**US3652038**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered empty.	System	25 Sep 2020 19:23:26

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered 'Yes (Y)'	Ashley Machado (b) (4)	25 Sep 2020 13:54:57

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered empty.	Ashley Machado (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered empty.	Ashley Machado (b) (4)	25 Sep 2020 13:54:57



US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered '25 Sep 2020'	Ashley Machado (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered '9:53'	Ashley Machado (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered '25 Sep 2020 9:53'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered 'Left Arm (LEFT ARM)'	Ashley Machado (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered 'ONCE'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:24:09



US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered '09:21'	Jiamin Li (b) (4)	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered '25 Sep 2020 09:21'	System	25 Sep 2020 19:24:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered '25 Sep 2020'	Jiamin Li (b) (4)	25 Sep 2020 19:23:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered '09:25'	Jiamin Li (b) (4)	25 Sep 2020 19:23:38

**US3652038**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered '25 Sep 2020 09:25'	System	25 Sep 2020 19:23:38



US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered 'No (N)'	Jiamin Li (b) (4)	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered empty.	Jiamin Li (b) (4)	25 Sep 2020 19:23:38

**US3652038**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered empty.	System	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User closed query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, V2D29 has not been completed, please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:13:12
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 08:12:42
Query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, V2D29 has not been completed, please review and reconcile, else clarify. ' answered with 'Dosing discontinued due to COVID-19 AE.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:55:02
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 'Further visits are recorded.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:54:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:47
User opened query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, V2D29 has not been completed, please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:45:46
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 14:58:26
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:44

**US3652038**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:09:00
User entered 'I'	System	25 Sep 2020 19:23:44

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:28:37', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7f5c3b0d-f6a7-44e9-be0f-a74be4c24ca3' User entered 'Yes (Y)'	System	25 Sep 2020 14:29:01
	System	25 Sep 2020 14:29:01



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:28:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7f5c3b0d-f6a7-44e9-be0f-a74be4c24ca3' User entered '97.9'	System	25 Sep 2020 14:29:01
	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:28:55', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7f5c3b0d-f6a7-44e9-be0f-a74be4c24ca3' User entered 'No (N)'	System	25 Sep 2020 14:29:01
	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:28:59', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7f5c3b0d-f6a7-44e9-be0f-a74be4c24ca3' User entered '25 Sep 2020 10:28'	System	25 Sep 2020 14:29:01
	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 10:13'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:21:35', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '35fd61bd-a1ea-4cef-99d3-ac9f0bcda54' User entered 'Yes (Y)'	System	25 Sep 2020 23:21:55
	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:21:41', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '35fd61bd-a1ea-4cef-99d3-ac9f0bcda54' User entered '97.6'	System	25 Sep 2020 23:21:55
	System	25 Sep 2020 23:21:55



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:21:45', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '35fd61bd-a1ea-4cef-99d3-ac9f0bcda54' User entered 'No (N)'	System	25 Sep 2020 23:21:55
	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:21:52', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '35fd61bd-a1ea-4cef-99d3-ac9f0bcda54' User entered '25 Sep 2020 19:21'	System	25 Sep 2020 23:21:55
	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 13:38'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 2'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:09:48', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484' User entered 'Yes (Y)'	System	26 Sep 2020 23:10:52
	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:10:26', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484' User entered '97.7'	System	26 Sep 2020 23:10:52
	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:10:32', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484'	System	26 Sep 2020 23:10:52
User entered 'Yes (Y)'	System	26 Sep 2020 23:10:52



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
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 'Ibuprofen recorded.' (Site from System).	(b) (4)	02 Dec 2020 17:06:38
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)	01 Dec 2020 03:00:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:10:42', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484'	(b) (4)	
User entered '1'	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:10:42', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484' User entered '0'	System	26 Sep 2020 23:10:52
	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:10:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '66f95ef9-9f59-40f4-bd2d-068b7a251484'	System	26 Sep 2020 23:10:52
User entered '26 Sep 2020 19:10'	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 3'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:14:19', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'e344b755-c805-4b86-a63f-4517f61f7add' User entered 'Yes (Y)'	System	28 Sep 2020 01:14:55
	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:14:48', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'e344b755-c805-4b86-a63f-4517f61f7add' User entered '96.4'	System	28 Sep 2020 01:14:55
	System	28 Sep 2020 01:14:55



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:14:50', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'e344b755-c805-4b86-a63f-4517f61f7add' User entered 'No (N)'	System	28 Sep 2020 01:14:55
	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:14:53', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'e344b755-c805-4b86-a63f-4517f61f7add' User entered '27 Sep 2020 21:14'	System	28 Sep 2020 01:14:55
	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 4'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:53:12', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'def7f241-b30e-41b6-b1d9-c894a3363f2d' User entered 'Yes (Y)'	System	29 Sep 2020 02:55:07
	System	29 Sep 2020 02:55:07

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:01', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'def7f241-b30e-41b6-b1d9-c894a3363f2d' User entered '96.8'	System	29 Sep 2020 02:55:07
	System	29 Sep 2020 02:55:07

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:03', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'def7f241-b30e-41b6-b1d9-c894a3363f2d' User entered 'No (N)'	System	29 Sep 2020 02:55:07
	System	29 Sep 2020 02:55:07



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:06', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'def7f241-b30e-41b6-b1d9-c894a3363f2d' User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:07
	System	29 Sep 2020 02:55:07

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 5'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 6'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:44:17', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6e3583aa-9804-4a7f-8d24-50e74a0d31f6' User entered 'Yes (Y)'	System	01 Oct 2020 01:45:16
	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:07', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6e3583aa-9804-4a7f-8d24-50e74a0d31f6' User entered '97.2'	System	01 Oct 2020 01:45:16
	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:10', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6e3583aa-9804-4a7f-8d24-50e74a0d31f6'	System	01 Oct 2020 01:45:16
User entered 'No (N)'	System	01 Oct 2020 01:45:16



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:12', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6e3583aa-9804-4a7f-8d24-50e74a0d31f6' User entered '30 Sep 2020 21:45'	System	01 Oct 2020 01:45:16
	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 7'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:11', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '145ba1cd-d47e-4f28-9b9f-50d8f0b1a2b3'	System	25 Sep 2020 14:29:31
User entered 'None (1)'	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:15', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '145ba1cd-d47e-4f28-9b9f-50d8f0b1a2b3' User entered 'No (N)'	System	25 Sep 2020 14:29:31
	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:20', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '145ba1cd-d47e-4f28-9b9f-50d8f0b1a2b3' User entered 'No (N)'	System	25 Sep 2020 14:29:31
	System	25 Sep 2020 14:29:31



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:24', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '145ba1cd-d47e-4f28-9b9f-50d8f0b1a2b3'	System	25 Sep 2020 14:29:31
User entered 'None (1)'	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:27', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '145ba1cd-d47e-4f28-9b9f-50d8f0b1a2b3' User entered '25 Sep 2020 10:29'	System	25 Sep 2020 14:29:31
	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 10:13'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:25', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ffe2c82e-2085-4061-ae74-2d0195811ef8'	System	25 Sep 2020 23:22:54
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:28', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ffe2c82e-2085-4061-ae74-2d0195811ef8' User entered 'No (N)'	System	25 Sep 2020 23:22:54
	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:33', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ffe2c82e-2085-4061-ae74-2d0195811ef8' User entered 'No (N)'	System	25 Sep 2020 23:22:54
	System	25 Sep 2020 23:22:54



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ffe2c82e-2085-4061-ae74-2d0195811ef8'	System	25 Sep 2020 23:22:54
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:52', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ffe2c82e-2085-4061-ae74-2d0195811ef8' User entered '25 Sep 2020 19:22'	System	25 Sep 2020 23:22:54
	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 13:38'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 2'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:02', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '97576165-fca7-4dfc-b964-efceb5c3f49e'	System	26 Sep 2020 23:11:41
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:05', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '97576165-fca7-4dfc-b964-efceb5c3f49e' User entered 'No (N)'	System	26 Sep 2020 23:11:41
	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:08', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '97576165-fca7-4dfc-b964-efceb5c3f49e' User entered 'No (N)'	System	26 Sep 2020 23:11:41
	System	26 Sep 2020 23:11:41



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:32', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '97576165-fca7-4dfc-b964-efceb5c3f49e'	System	26 Sep 2020 23:11:41
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 23:11:41

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:37', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '97576165-fca7-4dfc-b964-efceb5c3f49e' User entered '26 Sep 2020 19:11'	System	26 Sep 2020 23:11:41
	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 3'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:07', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ed54f05a-5bd5-48c5-b2f8-b84bdd906f0c'	System	28 Sep 2020 01:15:21
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:10', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ed54f05a-5bd5-48c5-b2f8-b84bdd906f0c' User entered 'No (N)'	System	28 Sep 2020 01:15:21
	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:12', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ed54f05a-5bd5-48c5-b2f8-b84bdd906f0c' User entered 'No (N)'	System	28 Sep 2020 01:15:21
	System	28 Sep 2020 01:15:21



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:15', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ed54f05a-5bd5-48c5-b2f8-b84bdd906f0c' User entered 'None (1)'	System	28 Sep 2020 01:15:21
	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:18', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ed54f05a-5bd5-48c5-b2f8-b84bdd906f0c' User entered '27 Sep 2020 21:15'	System	28 Sep 2020 01:15:21
	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 4'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:11', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '288fa04b-0c46-4e95-82a6-2fdc45d78436' User entered 'None (1)'	System	29 Sep 2020 02:55:24
	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:14', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '288fa04b-0c46-4e95-82a6-2fdc45d78436'	System	29 Sep 2020 02:55:24
User entered 'No (N)'	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:16', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '288fa04b-0c46-4e95-82a6-2fdc45d78436' User entered 'No (N)'	System	29 Sep 2020 02:55:24
	System	29 Sep 2020 02:55:24



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:19', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '288fa04b-0c46-4e95-82a6-2fdc45d78436' User entered 'None (1)'	System	29 Sep 2020 02:55:24
	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:21', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '288fa04b-0c46-4e95-82a6-2fdc45d78436' User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:24
	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 5'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 6'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:15', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '02aa21dd-9bd4-4422-b278-e1414c311452'	System	01 Oct 2020 01:45:24
User entered 'None (1)'	System	01 Oct 2020 01:45:24



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:17', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '02aa21dd-9bd4-4422-b278-e1414c311452'	System	01 Oct 2020 01:45:24
User entered 'No (N)'	System	01 Oct 2020 01:45:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:19', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '02aa21dd-9bd4-4422-b278-e1414c311452' User entered 'No (N)'	System	01 Oct 2020 01:45:24
	System	01 Oct 2020 01:45:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:20', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '02aa21dd-9bd4-4422-b278-e1414c311452'	System	01 Oct 2020 01:45:24
User entered 'None (1)'	System	01 Oct 2020 01:45:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:22', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '02aa21dd-9bd4-4422-b278-e1414c311452'	System	01 Oct 2020 01:45:24
User entered '30 Sep 2020 21:45'	System	01 Oct 2020 01:45:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 7'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:54:57



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:31', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:33', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:35', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:36', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:38', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:40', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'None (0)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:46', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered 'No (N)'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T10:29:48', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'd0ef8711-afd6-4da7-a6e3-6488ffdc8d7c' User entered '25 Sep 2020 10:29'	System	25 Sep 2020 14:29:53
	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 10:13'	System	25 Sep 2020 13:54:57

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:57', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:22:59', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:02', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:04', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:06', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:08', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'None (0)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:12', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered 'No (N)'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-25T19:23:15', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '24b39db2-9017-49a3-8c2a-e006b5a5d75d' User entered '25 Sep 2020 19:23'	System	25 Sep 2020 23:23:18
	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '25 Sep 2020 13:38'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 2'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:44', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470'	System	26 Sep 2020 23:12:07
User entered 'No interference with activity (1)'	System	26 Sep 2020 23:12:07



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470'	System	26 Sep 2020 23:12:07
User entered 'No interference with activity (1)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:49', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470'	System	26 Sep 2020 23:12:07
User entered 'No interference with activity (1)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:53', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470' User entered 'None (0)'	System	26 Sep 2020 23:12:07
	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:56', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470' User entered 'None (0)'	System	26 Sep 2020 23:12:07
	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:11:58', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470' User entered 'None (0)'	System	26 Sep 2020 23:12:07
	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:12:01', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470' User entered 'No (N)'	System	26 Sep 2020 23:12:07
	System	26 Sep 2020 23:12:07

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-26T19:12:03', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'b008d554-0459-4046-9eda-b8bbb2efd470' User entered '26 Sep 2020 19:12'	System	26 Sep 2020 23:12:07
	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 13:54:57



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 3'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:22', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:24', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:25', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:27', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:28', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:29', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'None (0)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:31', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered 'No (N)'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-27T21:15:33', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7405ee56-1b34-4d00-a899-95067bc81806' User entered '27 Sep 2020 21:15'	System	28 Sep 2020 01:15:36
	System	28 Sep 2020 01:15:36

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 4'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:26', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:28', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:29', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:31', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:32', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:34', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'None (0)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:35', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered 'No (N)'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-28T22:55:37', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '5fe76f46-9d38-4635-b5ef-29d565b9ec9a' User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:38
	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 5'	System	25 Sep 2020 13:54:57



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 6'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:26', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:27', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:28', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:29', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:30', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:31', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'None (0)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:34', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered 'No (N)'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-09-30T21:45:36', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '9ba2fbb6-0975-48df-8999-e5e123f3623d' User entered '30 Sep 2020 21:45'	System	01 Oct 2020 01:45:39
	System	01 Oct 2020 01:45:39

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:01:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
Data entry locked.	System	25 Sep 2020 13:54:57
User entered 'Day 7'	System	25 Sep 2020 13:54:57

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16



US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

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 14:00:16

US3652038

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:01:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 13:54:57

**US3652038**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:01:14**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:00:16
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 13:54:57



US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered '05 Oct 2020'	Genessi Rodriguez (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered 'Contact Made (CONTACT MADE)'	Genessi Rodriguez (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered empty.	Genessi Rodriguez (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:49
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	06 Oct 2020 20:56:53

**US3652038**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User entered 'I'	System	06 Oct 2020 20:56:53

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered '09 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 02:52:38



US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:58
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:52:43

**US3652038**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:08:54
User entered 'I'	System	22 Oct 2020 02:52:43

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered '16 Oct 2020'	Jiamin Li (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered empty.	Jiamin Li (b) (4)	22 Oct 2020 02:53:40



US3652038

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:08
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:53:45

**US3652038**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:49
User entered 'I'	System	22 Oct 2020 02:53:45

US3652038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:07:58

US3652038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:07:58

US3652038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:07:58

**US3652038**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:01:14**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'VISIT2'	System	24 Dec 2020 18:07:58

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:05
	(b) (4)	

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:05



US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05



US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:05



US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05
	(b) (4)	

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05



US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:05

US3652038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:10

US3652038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:10



US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User closed query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:53:45
Query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 15:51:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 15:51:22
User opened query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 07:11:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:14

US3652038

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:14



US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:30



US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:01
User entered empty.	System	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:01:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:30

US3652038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:37
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:35

US3652038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:37
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:35

US3652038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:49:37
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:35

US3652038

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:35

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:41
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:41



US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:41
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:41
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

**US3652038**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:41
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:41
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:08:41

**US3652038**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:08:41

US3652038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:49
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:08:47



US3652038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:08:47

US3652038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:57
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:12

US3652038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:57
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:12

US3652038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:57
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:12

US3652038

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:57
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:12

US3652038

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:48
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:16

**US3652038**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:10:16

US3652038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:47
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:20



US3652038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:47
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:20

US3652038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:47
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:20

US3652038

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:47
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:20

US3652038

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:39
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:24

US3652038

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:10:24

US3652038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:10
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:30

US3652038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:10
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:30

US3652038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:10
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:30



US3652038

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:48:10
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:10:30

US3652038

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:47:59
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:10:34

**US3652038**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:10:34

US3652038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:16

US3652038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:16

US3652038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:16

US3652038

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'VISIT3'	System	24 Dec 2020 18:11:16

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:20



US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:20



US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:20

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54

US3652038

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54



US3652038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:25

US3652038

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:25

US3652038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'No (N)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:28

US3652038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:28

US3652038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:28

US3652038

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered empty.	System	24 Dec 2020 18:11:28

US3652038

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:47:12
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:33

US3652038

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:11:33



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:21', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8' User entered 'Yes (Y)'	System	10 Dec 2020 16:18:06
	System	10 Dec 2020 16:18:06



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:30', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8' User entered 'No (N)'	System	10 Dec 2020 16:18:06
	System	10 Dec 2020 16:18:06

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:35', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8' User entered 'No (N)'	System	10 Dec 2020 16:18:06
	System	10 Dec 2020 16:18:06

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:43', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8' User entered 'Yes (Y)'	System	10 Dec 2020 16:18:06
	System	10 Dec 2020 16:18:06

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8'	System	10 Dec 2020 16:18:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 16:18:06

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-10T11:17:51', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '16f2e5f5-5071-48d0-aec1-d41dc94615f8' User entered '10 Dec 2020 11:17:51'	System	10 Dec 2020 16:18:06
	System	10 Dec 2020 16:18:06

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-17T09:46:38', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '3151f51f-f0cd-4b25-b056-2a13540fcb8e' User entered 'No (N)'	System	17 Dec 2020 14:46:45

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-17T09:46:41', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '3151f51f-f0cd-4b25-b056-2a13540fcb8e' User entered 'No (N)'	System	17 Dec 2020 14:46:45

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-17T09:46:44', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '3151f51f-f0cd-4b25-b056-2a13540fcb8e' User entered '17 Dec 2020 09:46:44'	System	17 Dec 2020 14:46:45
	System	17 Dec 2020 14:46:45

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-29T12:32:57', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ebdd1cee-7901-4727-827f-7331cc6fbe2f' User entered 'No (N)'	System	29 Dec 2020 17:33:04
	System	29 Dec 2020 17:33:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-29T12:32:58', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ebdd1cee-7901-4727-827f-7331cc6fbe2f' User entered 'No (N)'	System	29 Dec 2020 17:33:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2020-12-29T12:33:01', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ebdd1cee-7901-4727-827f-7331cc6fbe2f' User entered '29 Dec 2020 12:33:01'	System	29 Dec 2020 17:33:04
	System	29 Dec 2020 17:33:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-04T11:13:41', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '1f93c2b8-53f5-472d-a9a5-6505cbe1907c'	System	04 Jan 2021 16:13:48
User entered 'No (N)'	System	04 Jan 2021 16:13:48



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-04T11:13:43', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '1f93c2b8-53f5-472d-a9a5-6505cbe1907c'	System	04 Jan 2021 16:13:48
User entered 'No (N)'	System	04 Jan 2021 16:13:48

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-04T11:13:45', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '1f93c2b8-53f5-472d-a9a5-6505cbe1907c' User entered '04 Jan 2021 11:13:45'	System	04 Jan 2021 16:13:48
	System	04 Jan 2021 16:13:48

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-13T13:12:29', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'c7e65490-94fa-4028-8cfd-2a03987a26e2' User entered 'No (N)'	System	13 Jan 2021 18:12:38

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-13T13:12:31', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'c7e65490-94fa-4028-8cfd-2a03987a26e2'	System	13 Jan 2021 18:12:38
User entered 'No (N)'	System	13 Jan 2021 18:12:38

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-13T13:12:34', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'c7e65490-94fa-4028-8cfd-2a03987a26e2'	System	13 Jan 2021 18:12:38
User entered '13 Jan 2021 13:12:34'	System	13 Jan 2021 18:12:38



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-25T16:32:47', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'eeafdc3a-5df7-4347-9867-2090644f3d48'	System	25 Jan 2021 21:32:55
User entered 'No (N)'	System	25 Jan 2021 21:32:55

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-25T16:32:49', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'eeafdc3a-5df7-4347-9867-2090644f3d48'	System	25 Jan 2021 21:32:55
User entered 'No (N)'	System	25 Jan 2021 21:32:55



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-01-25T16:32:52', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'eeafdc3a-5df7-4347-9867-2090644f3d48' User entered '25 Jan 2021 16:32:52'	System	25 Jan 2021 21:32:55
	System	25 Jan 2021 21:32:55

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-16T10:31:55', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6b2a77e7-fa8f-410c-a74e-91753861512e' User entered 'No (N)'	System	16 Feb 2021 15:32:04
	System	16 Feb 2021 15:32:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-16T10:31:56', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6b2a77e7-fa8f-410c-a74e-91753861512e' User entered 'No (N)'	System	16 Feb 2021 15:32:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-16T10:31:59', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '6b2a77e7-fa8f-410c-a74e-91753861512e' User entered '16 Feb 2021 10:31:59'	System	16 Feb 2021 15:32:04
	System	16 Feb 2021 15:32:04

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-24T09:11:36-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab8b3ee8-23de-4ac3-83ae-88d257d5012a' User entered 'No (N)'	System	24 Feb 2021 14:12:08
	System	24 Feb 2021 14:12:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-24T09:11:39-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab8b3ee8-23de-4ac3-83ae-88d257d5012a' User entered 'No (N)'	System	24 Feb 2021 14:12:08
	System	24 Feb 2021 14:12:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-02-24T09:11:41-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab8b3ee8-23de-4ac3-83ae-88d257d5012a' User entered '24 Feb 2021 14:11:41'	System	24 Feb 2021 14:12:08
	System	24 Feb 2021 14:12:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-03T08:30:58-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '510e7ee7-f6e0-4861-aa89-75c42ed18658'	System	03 Mar 2021 13:31:17
User entered 'No (N)'	System	03 Mar 2021 13:31:17

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-03T08:31:00-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '510e7ee7-f6e0-4861-aa89-75c42ed18658'	System	03 Mar 2021 13:31:17
User entered 'No (N)'	System	03 Mar 2021 13:31:17



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-03T08:31:02-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '510e7ee7-f6e0-4861-aa89-75c42ed18658'	System	03 Mar 2021 13:31:17
User entered '03 Mar 2021 08:31:02'	System	03 Mar 2021 13:31:17

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-10T15:24:06-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'a6c393f9-a49a-4b2c-b58e-4b341c5d01d9'	System	10 Mar 2021 20:24:22
User entered 'No (N)'	System	10 Mar 2021 20:24:22

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-10T15:24:10-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'a6c393f9-a49a-4b2c-b58e-4b341c5d01d9'	System	10 Mar 2021 20:24:22
User entered 'No (N)'	System	10 Mar 2021 20:24:22

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-10T15:24:13-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'a6c393f9-a49a-4b2c-b58e-4b341c5d01d9'	System	10 Mar 2021 20:24:22
User entered '10 Mar 2021 15:24:13'	System	10 Mar 2021 20:24:22

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-16T15:31:27-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '64870060-9ec7-4192-a5d0-d0e6f0dc1f39'	System	16 Mar 2021 19:31:35
User entered 'No (N)'	System	16 Mar 2021 19:31:35

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-16T15:31:29-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '64870060-9ec7-4192-a5d0-d0e6f0dc1f39'	System	16 Mar 2021 19:31:35
User entered 'No (N)'	System	16 Mar 2021 19:31:35

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-16T15:31:33-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '64870060-9ec7-4192-a5d0-d0e6f0dc1f39'	System	16 Mar 2021 19:31:35
User entered '16 Mar 2021 15:31:33'	System	16 Mar 2021 19:31:35

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-25T08:55:18-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7cfc8f1f-ab1d-4a8a-a8a2-efa20184f111'	System	25 Mar 2021 12:55:28
User entered 'No (N)'	System	25 Mar 2021 12:55:28

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-25T08:55:23-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7cfc8f1f-ab1d-4a8a-a8a2-efa20184f111'	System	25 Mar 2021 12:55:28
User entered 'No (N)'	System	25 Mar 2021 12:55:28

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-25T08:55:25-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '7cfc8f1f-ab1d-4a8a-a8a2-efa20184f111'	System	25 Mar 2021 12:55:28
User entered '25 Mar 2021 08:55:25'	System	25 Mar 2021 12:55:28

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-01T10:57:30-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '19610e3e-27df-465b-9277-f3b10300a5a0'	System	01 Apr 2021 14:57:39
User entered 'No (N)'	System	01 Apr 2021 14:57:39

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-01T10:57:31-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '19610e3e-27df-465b-9277-f3b10300a5a0'	System	01 Apr 2021 14:57:39
User entered 'No (N)'	System	01 Apr 2021 14:57:39



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-01T10:57:34-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '19610e3e-27df-465b-9277-f3b10300a5a0'	System	01 Apr 2021 14:57:39
User entered '01 Apr 2021 10:57:34'	System	01 Apr 2021 14:57:39

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-05T12:09:00-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '15774a2e-0574-499a-8e59-7decc706cdf5'	System	05 Apr 2021 16:15:00
User entered 'No (N)'	System	05 Apr 2021 16:15:00

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-05T12:09:06-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '15774a2e-0574-499a-8e59-7decc706cdf5'	System	05 Apr 2021 16:15:00
User entered 'No (N)'	System	05 Apr 2021 16:15:00

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-05T12:09:08-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '15774a2e-0574-499a-8e59-7decc706cdf5'	System	05 Apr 2021 16:15:00
User entered '05 Apr 2021 12:09:08'	System	05 Apr 2021 16:15:00

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-12T14:53:09-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'f2d0f21c-9b34-4fe9-84ae-1926112bd876'	System	22 Apr 2021 23:27:08
User entered 'No (N)'	System	22 Apr 2021 23:27:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-12T14:53:10-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'f2d0f21c-9b34-4fe9-84ae-1926112bd876'	System	22 Apr 2021 23:27:08
User entered 'No (N)'	System	22 Apr 2021 23:27:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-12T14:53:13-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'f2d0f21c-9b34-4fe9-84ae-1926112bd876'	System	22 Apr 2021 23:27:08
User entered '12 Apr 2021 14:53:13'	System	22 Apr 2021 23:27:08

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-22T19:27:06-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '96941f8f-0679-4fa6-a40c-14cd85b6f291'	System	22 Apr 2021 23:27:13
User entered 'No (N)'	System	22 Apr 2021 23:27:13

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-22T19:27:08-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '96941f8f-0679-4fa6-a40c-14cd85b6f291' User entered 'No (N)'	System	22 Apr 2021 23:27:13
	System	22 Apr 2021 23:27:13

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-22T19:27:10-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: '96941f8f-0679-4fa6-a40c-14cd85b6f291'	System	22 Apr 2021 23:27:13
User entered '22 Apr 2021 19:27:10'	System	22 Apr 2021 23:27:13

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-26T11:37:01-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab9700e6-5288-4d9a-bec1-3dc774d0077a' User entered 'No (N)'	System	26 Apr 2021 15:37:10
	System	26 Apr 2021 15:37:10

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Have you been exposed to someone with 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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-26T11:37:03-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab9700e6-5288-4d9a-bec1-3dc774d0077a'	System	26 Apr 2021 15:37:10
User entered 'No (N)'	System	26 Apr 2021 15:37:10



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-04-26T11:37:06-04:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'ab9700e6-5288-4d9a-bec1-3dc774d0077a'	System	26 Apr 2021 15:37:10
User entered '26 Apr 2021 11:37:06'	System	26 Apr 2021 15:37:10

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 10:45:31



**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 10:45:31

**US3652038**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:01:14**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:45:31
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 10:45:31

US3652038

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Jun 2021 15:01:14**

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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-03T08:31:29-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'cb06b9bd-3ace-4d4e-889d-00a6b8cb437c' User entered 'No (N)'	System	03 Mar 2021 13:31:38
	System	03 Mar 2021 13:31:38

**US3652038**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Jun 2021 15:01:14**

[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 (0FB7F870-526D-4305-BB43-5E08B7DC8F34)', Time: '2021-03-03T08:31:33-05:00', User OID: 'PatientReportedOutcome (US3652038)', ODM File OID: 'cb06b9bd-3ace-4d4e-889d-00a6b8cb437c' User entered '03 Mar 2021 08:31:33'	System	03 Mar 2021 13:31:38
	System	03 Mar 2021 13:31:38

US3652038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:23:02
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:47

US3652038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:23:02
User entered '16 Dec 2020'	Jiamin Li (b) (4)	24 Dec 2020 18:11:47



US3652038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:23:02
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:47

US3652038

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:23:02
User entered empty.	Jiamin Li (b) (4)	24 Dec 2020 18:11:47

US3652038

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
DataPoint Verified.		14 Apr 2021 15:48:19
User signature succeeded.	Kristen Marks (b) (4)	26 Mar 2021 20:46:52
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Dec 2020 18:11:51
	(b) (4)	

**US3652038**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:14:54
User entered 'I'	System	24 Dec 2020 18:11:51

US3652038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:03
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Jan 2021 16:54:00

US3652038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:03
User entered '21 Jan 2021'	Jiamin Li (b) (4)	27 Jan 2021 16:54:00

US3652038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:03
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	27 Jan 2021 16:54:00

US3652038

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:03
User entered empty.	Jiamin Li (b) (4)	27 Jan 2021 16:54:00



US3652038

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:41
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Jan 2021 16:54:05

**US3652038**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User entered 'I'	System	27 Jan 2021 16:54:05

US3652038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:21
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:26:10

US3652038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:21
User entered '18 Feb 2021'	Jiamin Li (b) (4)	25 Feb 2021 23:26:10

US3652038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:21
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jiamin Li (b) (4)	25 Feb 2021 23:26:10

US3652038

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:21
User entered 'Participant did not pick up after multiple attempts'	Jiamin Li (b) (4)	25 Feb 2021 23:26:10

US3652038

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:13
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Feb 2021 23:26:32

**US3652038**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User entered 'I'	System	25 Feb 2021 23:26:32



US3652038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:38
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:03:41

US3652038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:38
User entered '23 Mar 2021'	Jiamin Li (b) (4)	31 Mar 2021 19:03:41

US3652038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:38
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	31 Mar 2021 19:03:41

US3652038

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:01:14

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:38
User entered empty.	Jiamin Li (b) (4)	31 Mar 2021 19:03:41

US3652038

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:46:30
User entered 'Yes (Y)'	Jiamin Li (b) (4)	31 Mar 2021 19:03:46

**US3652038**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:46:54
User entered 'I'	System	31 Mar 2021 19:03:46

US3652038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User entered 'Yes (Y)'	Sarah Galloway (b) (4) (b) (4)	13 Apr 2021 15:27:51

US3652038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User entered '13 Apr 2021'	Sarah Galloway (b) (4) (b) (4)	13 Apr 2021 15:27:51



US3652038

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User entered 'Clinic (Clinic)'	Sarah Galloway (b) (4) (b) (4)	13 Apr 2021 15:27:51

**US3652038**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:01:14**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 15:27:51

US3652038

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:35:33
User entered 'Yes (Y)'	Sarah Galloway (b) (4) (b) (4)	13 Apr 2021 15:27:56

**US3652038**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 15:27:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:01:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:01:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered '13:20'	Jiamin Li (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:01:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:54
User entered '27 Oct 2020 13:20'	System	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:01:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jiamin Li (b) (4)	02 Nov 2020 17:07:42



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:01:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:11:54
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User closed query 'Per CDM: Symptoms are missing for Day 10 and Day 13. Please verify if the missing data is available, otherwise please select Assessment Not Done for those days.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:08:07
Query 'Per CDM: Symptoms are missing for Day 10 and Day 13. Please verify if the missing data is available, otherwise please select Assessment Not Done for those days.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	25 Apr 2021 18:05:21
User opened query 'Per CDM: Symptoms are missing for Day 10 and Day 13. Please verify if the missing data is available, otherwise please select Assessment Not Done for those days.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 05:53:02
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:23:32
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:19:25
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '27 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '99'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '98.3' F reason for change: Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:20:29
User entered '98.3' C	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:09:08
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered '26 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User closed query 'Per CDM: Please, consider to un-check 'Assessment Not Done' for (Day 2 and 7) as 'Assessment Not Done' will only be checked or selected if the entire assessment was not completed. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:58:34
Query 'Per CDM: Please, consider to un-check 'Assessment Not Done' for (Day 2 and 7) as 'Assessment Not Done' will only be checked or selected if the entire assessment was not completed. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 15:47:17
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:47:13
User opened query 'Per CDM: Please, consider to un-check 'Assessment Not Done' for (Day 2 and 7) as 'Assessment Not Done' will only be checked or selected if the entire assessment was not completed. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:15:24
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 03:01:30
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:47:13
User closed query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'No Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4)	02 Dec 2020 17:01:09
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 03:01:35
User opened query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'No Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	04 Feb 2021 15:47:13
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered empty.	System	02 Nov 2020 17:10:02

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:47:13
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 15:43:01
DataPoint Un-verified.		2 Nov 2020 04:15:40
DataPoint Verified.		1 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02



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Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:19
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:17
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:02

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'Day 1 (Day 1)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered '25 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
Query 'Per CDM:Requery:Response noted,however for day 2 and 7 data has not been updated. Kindly review and update accordingly. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:14:31
User opened query 'Per CDM:Requery:Response noted,however for day 2 and 7 data has not been updated. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:32:14
User closed query 'Per CDM: Assessment Not Done is checked for days 1, 2 and 7, yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:30:21
Query 'Per CDM: Assessment Not Done is checked for days 1, 2 and 7, yet data is present. Please review and reconcile.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:50:46
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:50:43
User opened query 'Per CDM: Assessment Not Done is checked for days 1, 2 and 7, yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 16:38:48
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 03:01:49
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57



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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:50:43
User closed query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'No Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 17:01:32
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 03:01:54
User opened query 'Per CDM: If 'O2 saturation and temperature' was not assessed consider to update 'No Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	26 Jan 2021 14:50:43
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	(b) (4)	02 Nov 2020 17:19:14
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:10:57
	System	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:50:43
DataPoint Un-verified.	(b) (4)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	03 Nov 2020 15:23:23
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	02 Nov 2020 17:19:14
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:23:42
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '28 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '99'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	02 Nov 2020 17:20:21



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '36.6' C	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	



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Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:20:21
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:23:52
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '29 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '99'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered '36.7' C	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.		12 Nov 2020 04:15:40
DataPoint Verified.		11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36
	(b) (4)	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:24:36

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:24:01
User entered 'Day 4 (Day 4)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '30 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '99'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '36.9' C	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:27:31

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:24:09
User entered 'Day 5 (Day 5)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '31 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:49:06
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 03:02:04
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:49:06
User closed query 'Per CDM: If 'O2 saturation and temperature' were not assessed consider to update 'Not Done'. The symptom response cannot be left blank. Please reconcile and update accordingly.' (Site from DM).	(b) (4)	02 Dec 2020 17:02:10
Query 'Per CDM: If 'O2 saturation and temperature' were 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 03:02:09
User opened query 'Per CDM: If 'O2 saturation and temperature' were 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 06:11:16
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	04 Feb 2021 15:49:06
User entered empty.	System	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Jiamin Li (b) (4)	04 Feb 2021 15:49:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:24:17
User entered 'Day 6 (Day 6)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '01 Nov 2020'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '99'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	02 Nov 2020 22:21:13



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '97.9' F	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 11 (Day 11)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '04 Nov 2020'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '100'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '98.8' F	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 9 (Day 9)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '02 Nov 2020'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '0'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '98'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered '97.4' F	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:47
User entered 'None (None)'	Jiamin Li (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 12 (Day 12)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '05 Nov 2020'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '0'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '99'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '98.2' F	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 14 (Day 14)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '07 Nov 2020'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '0'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '99'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	13 Nov 2020 21:31:30



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '96.8' F	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 15 (Day 15)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '08 Nov 2020'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '0'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '99'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '97.7' F	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User entered 'Day 16 (Day 16)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '09 Nov 2020'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '0'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '99'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered '%'	System	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered '97.1' F	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:01
User entered 'None (None)'	Jiamin Li (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User entered 'Day 10 (Day 10)'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered '03 Nov 2020'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered 'I'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered empty.	System	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49
DataPoint activated with code reason code Data required.	Jiamin Li (b) (4)	25 Apr 2021 18:04:10
DataPoint inactivated with code reason code Data not required.	Jiamin Li (b) (4)	17 Dec 2020 19:44:18

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User entered 'Day 13 (Day 13)'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered '06 Nov 2020'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered 'I'	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User entered empty.	System	25 Apr 2021 18:04:49



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Jun 2021 15:01:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:06
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:39
User entered empty.	Jiamin Li (b) (4)	25 Apr 2021 18:04:49

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered '27 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:33:48
User entered '26 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[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 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[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 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
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)	10 Nov 2020 16:14:13
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 17:13:25
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 17:12:56
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered '27 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:33:48
User entered '26 Oct 2020'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[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 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:33:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:33:48
User entered 'City MD'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	03 Nov 2020 15:33:48
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Jun 2021 15:01:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:18
User entered 'I'	System	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

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 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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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 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
User closed query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:58:06
Query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:49:02
User opened query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:26:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:45
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:15:16
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:45
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:15:16
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:45
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:15:16
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

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DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:45
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:49:23
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	02 Nov 2020 17:15:16
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48



US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:45
User closed query 'Per CDM: Please review Radiographical Evidence section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:58:24
Query 'Per CDM: Please review Radiographical Evidence section and update accordingly as it appears some responses are missing.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:49:12
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:48:57
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:48:57
User opened query 'Per CDM: Please review Radiographical Evidence section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 16:43:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[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 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Jun 2021 15:01:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:46
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 15:01:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:13:00
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:24
User entered 'No (N)'	Jiamin Li (b) (4)	02 Nov 2020 17:15:24

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:01:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:48:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'This is a PPD error. We are in process of correcting date in PPD.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	26 Jan 2021 14:52:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:43:30
User accepted default value 'Day 3 (Day 3)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37



US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 17:23:41
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 07:31:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:32
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)	02 Feb 2021 15:48:49
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 'This is a PPD error. We are in process of correcting date in PPD.' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:52:30
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).	(b) (4), (b) (6)	29 Dec 2020 08:42:34
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)	28 Dec 2020 05:34:15

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
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 'After confirming with the lab, PPD needs to be changed to 29OCT2020, which is the correct date.' (Site from DM).	Jiamin Li (b) (4)	24 Dec 2020 18:14:06
DataPoint Un-verified.	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Dec 2020 18:13:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 20:26:57
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 04:43:20
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 04:43:20
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)	17 Dec 2020 19:48:16
DataPoint Un-verified.	(b) (4)	
	Jiamin Li (b) (4)	17 Dec 2020 19:48:10
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	17 Dec 2020 19:48:10
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 08:29:18
	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered '29 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:01:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
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)	18 Dec 2020 04:44:01
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)	17 Dec 2020 19:48:22
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)	02 Dec 2020 08:46:34
User accepted default value 'Day 5 (Day 5)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
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 08:56:34
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)	19 Nov 2020 18:35:03
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 10:46:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 17:24:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:20:29
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
User entered '31 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:57:01
DataPoint Un-verified.	Jiamin Li (b) (4)	19 Nov 2020 18:34:58
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	19 Nov 2020 18:34:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered '31 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

**US3652038**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User accepted default value 'Day 7 (Day 7)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37



US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User closed query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:34:31
Query 'Per CDM: Please consider to record after receiving data. Thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	06 Nov 2020 12:53:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 12:53:03
User opened query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:53:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:52:38
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:13
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered '02 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	06 Nov 2020 12:53:03
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

**US3652038**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Jun 2021 15:01:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User accepted default value 'Day 9 (Day 9)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User closed query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:34:54
Query 'Per CDM: Please consider to record after receiving data. Thank you.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	06 Nov 2020 12:53:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 12:53:15
User opened query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:54:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:53:50
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:20
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered '04 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	06 Nov 2020 12:53:15
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

**US3652038**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User accepted default value 'Day 14 (Day 14)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
DataPoint Un-verified.	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User closed query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:35:33
Query 'Per CDM: Please consider to record after receiving data. Thank you.' answered with 'Form will be completed once visit occurs.' (Site from DM).	Jiamin Li (b) (4)	05 Nov 2020 21:55:30
User opened query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:55:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:54:51
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:27
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
DataPoint Un-verified.	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
User entered '09 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37



US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:01:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User accepted default value 'Day 21 (Day 21)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
DataPoint Un-verified.	Jiamin Li (b) (4)	07 Dec 2020 16:28:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	07 Dec 2020 16:28:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User closed query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:35:44
Query 'Per CDM: Please consider to record after receiving data. Thank you.' answered with 'Form will be completed once visit occurs.' (Site from DM).	Jiamin Li (b) (4)	05 Nov 2020 21:56:31
User opened query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:56:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:55:40
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 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)	01 Dec 2020 12:36:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 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. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:57:47
DataPoint Un-verified.	Jiamin Li (b) (4)	01 Dec 2020 02:57:43
User entered '16 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:57:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 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)	26 Nov 2020 07:43:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

**US3652038**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Jun 2021 15:01:14**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User accepted default value 'Day 28 (Day 28)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Jun 2021 15:01:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
DataPoint Un-verified.	Ashley Machado (b) (4)	24 Nov 2020 15:05:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Machado (b) (4)	24 Nov 2020 15:05:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User closed query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:35:49
Query 'Per CDM: Please consider to record after receiving data. Thank you.' answered with 'Form will be completed once visit occurs.' (Site from DM).	Jiamin Li (b) (4)	05 Nov 2020 22:04:28
User opened query 'Per CDM: Please consider to record after receiving data. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:57:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:56:25
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:39
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:48
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:26:57
DataPoint Un-verified.	Ashley Machado (b) (4)	24 Nov 2020 15:05:27
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 15:05:27
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:55
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:55
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:34:06



US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[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 10:22:58
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:55
User entered 'Home (Home)' reason for change:	Jiamin Li (b) (4)	03 Nov 2020 15:34:15
Data Entry Error	(b) (4)	
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	03 Nov 2020 15:34:06
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:22:58
User entered 'SICKD1'	System	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:40:41
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:36:25
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User entered empty.	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:40:39
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:36:27
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
DataPoint set to visible.	System	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:40:43
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:36:29
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
DataPoint set to visible.	System	03 Nov 2020 15:34:06



US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '98.3' F	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:40:46
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:36:32
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '74'	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

**US3652038**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:01:14**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User entered 'bpm'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 13:40:48
Query 'Data is required. Please provide.' answered with 'Information not evaluated' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:36:35
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User entered empty.	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '98'	Jiamin Li (b) (4)	03 Nov 2020 15:36:18



US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User entered 'mmHg'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '70'	Jiamin Li (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07
User entered 'mmHg'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:07

US3652038

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:16
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:38:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:16
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:16
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:38:06

US3652038

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Jun 2021 15:01:14

[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 10:23:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:21
User entered 'Yes (Y)'	Jiamin Li (b) (4)	03 Nov 2020 15:38:34



US3652038

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:23:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:21
User entered '27 Oct 2020'	Jiamin Li (b) (4)	03 Nov 2020 15:38:34

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:16
User entered 'Yes (Y)'	Ashley Machado (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:16
User entered '24 Nov 2020'	Ashley Machado (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[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
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:16
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'SICKD28'	System	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '24 Nov 2020'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '09:35'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30



US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[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 '24 Nov 2020 09:35'	System	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '162.6' cm	Jiamin Li (b) (4)	24 Nov 2020 16:30:30
DataPoint set to visible.	(b) (4) System	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '56.2' kg	Jiamin Li (b) (4)	24 Nov 2020 16:30:30
DataPoint set to visible.	(b) (4) System	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '36.4' C	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered empty.	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '96'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User entered 'bpm'	System	24 Nov 2020 16:30:30



US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '17'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[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	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '123'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[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	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:20
User entered '68'	Jiamin Li (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

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	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:01:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52



US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:11
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Nov 2020 16:31:02

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:01:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:11
User entered '24 Nov 2020'	Jiamin Li (b) (4)	24 Nov 2020 16:31:02

US3652038

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Jun 2021 15:01:14

[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
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:06
User entered 'Yes (Y)'	Jiamin Li (b) (4)	24 Nov 2020 16:31:42

US3652038

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Jun 2021 15:01:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:14:52
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:27:06
User entered '24 Nov 2020'	Jiamin Li (b) (4)	24 Nov 2020 16:31:42

US3652038

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

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:14
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:10

US3652038

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

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:14
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:10

US3652038

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

Form: Visit Date

Generated On: 11 Jun 2021 15:01:14

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

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:14
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:10

**US3652038**

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

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:01:14**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	05 Apr 2021 20:11:10



US3652038

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

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
User closed query 'Per CDM, per Sponsor Review: On unblinding form, "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" is ticked, however, "Study Discontinuation" form is not present or completed. Please add or complete "Study Discontinuation" form. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:14:04
Query 'Per CDM, per Sponsor Review: On unblinding form, "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" is ticked, however, "Study Discontinuation" form is not present or completed. Please add or complete "Study Discontinuation" form. ' answered with 'Consent could not be taken because amendment 6 was not out at this time point. ' (Site from DM).	Jiamin Li (b) (4) (b) (4)	25 Apr 2021 18:07:55
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User opened query 'Per CDM, per Sponsor Review: On unblinding form, "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" is ticked, however, "Study Discontinuation" form is not present or completed. Please add or complete "Study Discontinuation" form. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 00:46:31
User entered 'I'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'Amendment 5 (Amendment 5)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered '05 Dec 2020'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'mRNA-1273 (mRNA-1273)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'mRNA-1273 (mRNA-1273)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'Not Administered (NA)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53



US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:01:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:56
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:10:53

**US3652038**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Jun 2021 15:01:14**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:10:53

**US3652038**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Jun 2021 15:01:14**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:10:53

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:15
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:14

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:15
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:14

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:44:15
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:14

**US3652038**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:01:14**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:11:14

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:01:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:42
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:22



US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:01:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:42
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:22

US3652038

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:01:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:42
User entered empty.	Jiamin Li (b) (4) (b) (4)	05 Apr 2021 20:11:22

**US3652038**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Jun 2021 15:01:14**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:11:22

US3652038

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 15:01:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:14:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:57:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:51:22

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:07:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:07:07
Data point term sent to Coder	System	22 Oct 2020 02:52:42
User entered 'Headache'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03



US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '07 Oct 2020'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 02:52:03

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 02:52:12
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Oct 2020 02:52:12
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	22 Oct 2020 02:52:03
User entered 'Yes (Y)'	System	22 Oct 2020 02:52:03
	Jiamin Li (b) (4)	22 Oct 2020 02:52:03
	(b) (4)	

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '07 Oct 2020'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03



**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03



US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'I'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03



**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 02:52:03

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:27:37
User entered 'USA-US132-2020-mRNA-1273-P301000001'	System	04 Nov 2020 15:27:30
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:27:30

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
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 15:04:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Nov 2020 15:04:20
Data point term sent to Coder	System	03 Nov 2020 15:03:20
User entered 'COVID-19'	Jiamin Li (b) (4)	03 Nov 2020 15:03:19
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:25:26
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) (b) (4)	16 Nov 2020 15:43:08
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:43:04
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 13:20:52
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: It was reported the subject began to experience symptoms on 25 Oct 2020 but event onset was reported as 28 Oct 2020. Please consider updating event start date to onset date of symptoms (25 Oct 2020) or clarify. Were symptoms prior to 28 Oct 2020 considered related to COVID-19?' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:11:17
Query 'PV Query: It was reported the subject began to experience symptoms on 25 Oct 2020 but event onset was reported as 28 Oct 2020. Please consider updating event start date to onset date of symptoms (25 Oct 2020) or clarify. Were symptoms prior to 28 Oct 2020 considered related to COVID-19?' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:44:06
User entered '25 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:43:56
User opened query 'PV Query: It was reported the subject began to experience symptoms on 25 Oct 2020 but event onset was reported as 28 Oct 2020. Please consider updating event start date to onset date of symptoms (25 Oct 2020) or clarify. Were symptoms prior to 28 Oct 2020 considered related to COVID-19?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:54:10
User entered '28 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:33:04
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) (b) (4)	24 Nov 2020 16:28:32
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:28:22
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)	09 Nov 2020 18:37:52
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '06 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Nov 2020 16:28:22
User entered empty.	(b) (4)	
	Jiamin Li (b) (4)	03 Nov 2020 15:03:19
	(b) (4)	



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**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: It was reported the event of COVID-19 was related to study procedure. Please provide the rationale for assessing the event of COVID-19 as related to study procedure.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:11:34
Query 'PV Query: It was reported the event of COVID-19 was related to study procedure. Please provide the rationale for assessing the event of COVID-19 as related to study procedure.' answered with 'Corrected' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:44:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:44:38
User opened query 'PV Query: It was reported the event of COVID-19 was related to study procedure. Please provide the rationale for assessing the event of COVID-19 as related to study procedure.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:37:38
User entered 'Related (RELATED)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

Action taken with investigational product

Audit	User	Time (GMT)
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)	28 Jan 2021 09:23:10
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 'Instructed by DM to change the reason for dosing discontinuation to be related to COVID-19.' (Site from System).	Jiamin Li (b) (4) (b) (4)	27 Jan 2021 16:51:41
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	26 Jan 2021 14:51:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
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 05:33:22
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 02:58:17
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).	System	01 Dec 2020 02:58:06
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 by data change (Site from System).	System	01 Dec 2020 02:58:06
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 16:54:52

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Action taken with investigational product

Audit	User	Time (GMT)
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 17:55:11
User closed query 'PV Query: Action taken was reported as "None" however, first and last reported dose was on 25 Sep 2020. Did the subject receive a second dose of mRNA-1273 prior to event onset date of 28 Oct 2020? If not, please consider updating the action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:11:39
Query 'PV Query: Action taken was reported as "None" however, first and last reported dose was on 25 Sep 2020. Did the subject receive a second dose of mRNA-1273 prior to event onset date of 28 Oct 2020? If not, please consider updating the action taken to withdrawn.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:45:07
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:44:59
User opened query 'PV Query: Action taken was reported as "None" however, first and last reported dose was on 25 Sep 2020. Did the subject receive a second dose of mRNA-1273 prior to event onset date of 28 Oct 2020? If not, please consider updating the action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:36:32
User entered 'None (NONE)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'I'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:33:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:28:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:28:22
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:38:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:48:48
User closed query 'PV Query: Please provide results for the COVID-19 saliva collections taken on 29 Oct 2020 and 31 Oct 2020 as well as any other COVID-19 testing along with results.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 23:48:46



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT IS A 34 Y.O FEMALE ENROLLED ON 9/25/2020. SHE HAD NO SIGNIFICANT MEDICAL HISTORY AND REPORTED HERSELF AS AT RISK OF COVID FROM HER WORK AND SUBWAY COMMUTE AS A HEALTH CARE PROVIDER. SHE RECEIVED HER FIRST INJECTION ON 9/25/2020. HER SECOND INJECTION WAS SCHEDULED ON 10/27/2020. HOWEVER, ON 10/26/2020, THE PT REACHED OUT TO STUDY TO REPORT COVID-LIKE SYMPTOMS POST A KNOWN EXPOSURE. SHE 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 10/22/2020 AT LOCAL URGENT CARE. ON 10/25/2020, SHE DEVELOPED MILD TO MODERATE DIARRHEA, NAUSEA, AND FATIGUE. SHE REPEATED PCR TESTING ON 10/26/2020 AND TESTED POSITIVE AT MT SINAI. SHE WAS SEEN ON 10/27/2020 BY STUDY CLINICIANS, WHERE SHE CONTINUED TO REPORT FATIGUE, NAUSEA, DIARRHEA ALL RATED AS MILD TO MODERATE. HER VITALS WERE STABLE T:98.3, 98/70, HR 74, O2 sat 99%. SHE WAS RETESTED BY VIRACOR PCR (POSITIVE REPORT 10/31/2020). NO MEDICAL INTERVENTION FOR HER SYMPTOMS WERE REQUIRED AT HER VISIT OR THEREAFTER. PT WAS MONITORED VIA TELEVITISS FOR THE NEXT 14 DAYS. DURING THIS TIME, HER O2 STATS REMAINED ABOVE 97% AND HER TEMPERATURE REMAINED NORMAL AND SHE REQUIRED NO MEDICAL INTERVENTION. SHE REPORTED SYMPTOM RESOLUTION BY 10/28/2020. SALIVA WAS COLLECTED PER PROTOCOL ON DAY 3, 5, 7, 9, 14, AND 21. SALIVA DAY 3 AND 7 RETURNED POSITIVE.	Jiamin Li (b) (4) (b) (4)	19 Nov 2020 16:33:43

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
SALIVA DAYS 5 AND 9 WERE REPORTED AS NOT 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		
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Results provided.' (Site from Safety).	Jiamin Li (b) (4)	19 Nov 2020 15:59:35
Query 'PV Query: Please provide results for the COVID-19 saliva collections taken on 29 Oct 2020 and 31 Oct 2020 as well as any other COVID-19 testing along with results.' answered with 'Results provided.' (Site from Safety).	Jiamin Li (b) (4)	19 Nov 2020 15:59:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant is a 34 y.o female enrolled on 9/25/2020. She had no significant medical history and reported herself as at risk of COVID from her work and subway commute as a health care provider. She received her first injection on 9/25/2020. Her second injection was scheduled on 10/27/2020. However, on 10/26/2020, the pt reached out to study to report COVID-like symptoms post a known exposure. She 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 10/22/2020 at local urgent care. On 10/25/2020, she developed mild to moderate diarrhea, nausea, and fatigue. She repeated PCR testing on 10/26/2020 and tested positive at Mt Sinai. She was seen on 10/27/2020 by study clinicians, where she continued to report fatigue, nausea, diarrhea all rated as mild to moderate. Her vitals were stable. She was retested by Viracor PCR (positive report 10/31/2020). No medical intervention for her symptoms were required at her visit or thereafter. Pt was monitored via televisit for the next 14 days. During this time, her O2 stats remained above 97% and her temperature remained normal and she required no medical intervention. She reported symptom resolution by 10/28/2020. Saliva was collected per protocol on Day 3, 5, 7, 9, 14, and 21. Saliva Day 3 and 7 returned positive. Saliva days 5 and 9 were reported as not 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) (b) (4)	19 Nov 2020 15:55:37
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:12:04

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Did the subject have any known Covid-19 exposure?' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:11:59
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 18:11:50
Query 'PV Query: Did the subject have any known Covid-19 exposure?' answered with 'Yes. Participant was exposed to an individual who tested positive on 10/21/2020. Pt's daughter tested positive on 10/22/2020. ' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:51:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'All medical treatments updated.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:50:15
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'None' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Nov 2020 15:49:53
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:50:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:38:26
User opened query 'PV Query: Did the subject have any known Covid-19 exposure?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:38:07
User opened query 'PV Query: Please provide results for the COVID-19 saliva collections taken on 29 Oct 2020 and 31 Oct 2020 as well as any other COVID-19 testing along with results.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:37:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:36:46
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:03:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 15:03:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 15:03:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:07:36
User entered 'USA-US132-2020-mRNA-1273-P301000003'	System	05 Dec 2020 19:07:20
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:07:20
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:39:40
User entered 'USA-US132-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	05 Dec 2020 18:29:46



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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Was final diagnosis determined (Differential included COVID related/ vaccine related or other etiology)?' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:38:13
User closed query 'PV Query: Please consider updating the event term to the final diagnosis when available. If to remain as "acute left pica territory infarct (symptoms began 11/30/2020, officially diagnosis and site awareness of SAE 12/4/2020), " please consider updating to acute left pica territory infarct.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:38:10
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 11:04:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 11:04:01
Data point term sent to Coder	System	17 Dec 2020 21:36:10
User entered 'CRYPTOGENIC STROKE (Official diagnosis on 12/4, symptoms beginning on 11/30)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:35:52
Query 'PV Query: Was final diagnosis determined (Differential included COVID related/ vaccine related or other etiology)?' answered with 'Related' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:35:12
Data point term sent to Coder	System	17 Dec 2020 21:34:08
Query 'PV Query: Please consider updating the event term to the final diagnosis when available. If to remain as "acute left pica territory infarct (symptoms began 11/30/2020, officially diagnosis and site awareness of SAE 12/4/2020), " please consider updating to acute left pica territory infarct.' answered with 'Final diagnosis term updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:33:33
Coding entries removed.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:33:27
User entered 'Cryptogenic Stroke' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:33:27

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was final diagnosis determined (Differential included COVID related/ vaccine related or other etiology)?' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:58:58
User opened query 'PV Query: Please consider updating the event term to the final diagnosis when available. If to remain as "acute left pica territory infarct (symptoms began 11/30/2020, officially diagnosis and site awareness of SAE 12/4/2020), " please consider updating to acute left pica territory infarct.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:58:02
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebellar artery thrombosis, LLT: Posterior inferior cerebellar artery thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:45:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 17:45:52
Data point term sent to Coder	System	04 Dec 2020 22:28:33
User entered 'Acute Left PICA Territory Infarct (Symptoms began 11/30/2020, officially diagnosis and site awareness of SAE 12/4/2020)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 22:28:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 22:28:51
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	04 Dec 2020 22:28:51
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 22:27:51
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '30 Nov 2020'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 22:27:51



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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:23:39
DataPoint Un-verified.	Jiamin Li (b) (4)	25 Apr 2021 17:56:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Apr 2021 17:56:42
DataPoint Verified.	Jiamin Li (b) (4)	25 Apr 2021 17:56:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 16:52:47
DataPoint Un-verified.	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 16:51:04
DataPoint Verified.	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	23 Dec 2020 19:17:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	17 Dec 2020 21:34:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 21:33:58
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 21:33:58
	(b) (4)	04 Dec 2020 22:27:51

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:23:39
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	25 Apr 2021 17:57:06
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	25 Apr 2021 17:57:06
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	25 Apr 2021 17:56:42
DataPoint Un-verified.	Jiamin Li (b) (4)	25 Apr 2021 17:56:42
User entered '15 Dec 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Apr 2021 17:56:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:09
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 16:52:47
DataPoint Un-verified.	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
User entered '02 Dec 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:38:20
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	17 Dec 2020 21:34:49
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	17 Dec 2020 21:34:49
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	17 Dec 2020 21:34:49

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	17 Dec 2020 21:34:07
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	17 Dec 2020 21:33:58
User entered '08 Dec 2020' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:33:58
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)	11 Dec 2020 17:56:50
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 21:24:44
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)	23 Dec 2020 13:19:02
User entered empty.	System	04 Dec 2020 22:27:51

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Dec 2020 22:28:51
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	04 Dec 2020 22:27:51
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 05:30:25
DataPoint Verified.	(b) (4), (b) (6)	28 Dec 2020 15:45:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated' (Site from System).	Jiamin Li (b) (4)	24 Dec 2020 18:05:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	Jiamin Li (b) (4)	24 Dec 2020 18:03:57
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 19:18:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4)	04 Dec 2020 22:27:51

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Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Dec 2020 15:45:25
User entered '04 Dec 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Dec 2020 18:05:48
DataPoint Un-verified.	(b) (4)	
	Jiamin Li (b) (4)	24 Dec 2020 18:04:38
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jiamin Li (b) (4)	24 Dec 2020 18:04:38
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:27:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Dec 2020 15:45:26
DataPoint Un-verified.	Jiamin Li (b) (4)	24 Dec 2020 18:05:48
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4)	24 Dec 2020 18:05:48
DataPoint Verified.	Jiamin Li (b) (4)	24 Dec 2020 18:05:48
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 19:18:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:27:51
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 19:18:32
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 19:18:34
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51



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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	04 Dec 2020 22:28:51
User entered '0'	Jiamin Li (b) (4)	04 Dec 2020 22:27:51

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Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug(s).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	06 Mar 2021 21:21:09
	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	17 Dec 2020 21:35:27
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	04 Dec 2020 22:27:51
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User closed query 'PV Query: Please assess action taken with study drug. Was study drug discontinued due to another event, prior to the start of this event? If so please consider updating action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:38:27
Query 'PV Query: Please assess action taken with study drug. Was study drug discontinued due to another event, prior to the start of this event? If so please consider updating action taken to Not Applicable.' answered with 'Drug discontinued due to another event. Status updated.' (Site from Safety).	Jiamin Li (b) (4)	17 Dec 2020 21:36:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 21:36:11
User opened query 'PV Query: Please assess action taken with study drug. Was study drug discontinued due to another event, prior to the start of this event? If so please consider updating action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:59:21
User entered 'None (NONE)'	Jiamin Li (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
Query 'PV Query: Please provide any additional treatment provided or treatment plan for the event. If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:02:53
User opened query 'PV Query: Please provide any additional treatment provided or treatment plan for the event. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:02:36
User entered 'I'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered 'I'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:23:39
User closed query 'PV Query: As subject has ongoing headache secondary to stroke, please consider updating event outcome to resolved with sequalee of headache.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:36:33
Query 'PV Query: As subject has ongoing headache secondary to stroke, please consider updating event outcome to resolved with sequalee of headache.' answered with 'Outcome and end date provided' (Site from Safety).	Jiamin Li (b) (4)	25 Apr 2021 17:58:01
DataPoint Un-verified.	Jiamin Li (b) (4)	25 Apr 2021 17:57:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Apr 2021 17:57:06
User opened query 'PV Query: As subject has ongoing headache secondary to stroke, please consider updating event outcome to resolved with sequalee of headache.' (Site from Safety).	(b) (4), (b) (6)	24 Apr 2021 15:59:09
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:09
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 13:56:56
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Headache related to the stroke is still ongoing, but stroke event is closed. Should I add the headache (which is a residual after-effect) as a separate log line?' (Site from Safety).	Jiamin Li (b) (4)	04 Feb 2021 15:49:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 18:47:51



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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:25:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 16:52:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	27 Jan 2021 16:51:10
DataPoint Un-verified.	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 16:51:04
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:57:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jiamin Li (b) (4)	04 Dec 2020 22:27:51

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT IN COVE MRNA-1273-P301 RECEIVED INJECTION #1 ON 9/25/20. PRIOR TO RECEIVING INJECTION #2 SHE DEVELOPED COVID SX. TESTED AT OUTSIDE FACILITY ON 10/26/20, COVID WAS CONFIRMED AS PER STUDY PROCEDURE ON 10/27/20. COVID CLINICAL COURSE WAS UNEVENTFUL, NOT REQUIRING ER OR MD VISIT, SX WERE MILD-MODERATE. PATIENT WAS SEEN IN ED ON MONDAY 11/30 AFTER SHE ACUTELY DEVELOPED NAUSEA/VOMITING AND DIFFICULTY WALKING DUE TO THE SENSATION OF BEING PULLED TO ONE SIDE. SHE WAS GIVEN ZOFRAN X 1 DOSE IN ED AND WAS SENT HOME ON MECLIZINE 25 MG PO TWICE DAILY WITH A PRESUMED DX OF VERTIGO. HER SYMPTOMS WERE IMPROVING BUT SHE CONTINUED TO HAVE SOME VERTIGO WITH ASSOCIATED HEADACHE AND NAUSEA. SHE SAW A NEUROLOGIST ON 12/2/20 WHO DID BLOODWORK AND HER CBC AND CRP LEVELS WERE NORMAL. THE WORKING DIAGNOSIS AT THAT TIME WAS VESTIBULAR NEURITIS BUT SHE IS SCHEDULED FOR AN MRI ON 12/4 TO RULE OUT OTHER CONDITIONS. 12/4/20 MRI: ACUTE LEFT PICA TERRITORY INFARCT MASS EFFECT ON THE FOURTH VENTRICLE MRA H/N-UNREMARKABLE 12/4/20: PT OBTAINED A SECOND OPINION AND WAS ADMITTED TO MT SINAI/BROOKLYN TO THE NEURO ICU. PT WAS UNBLINDED PER PROTOCOL AND ANGIOGRAM, LP, TEE PERFORMED. ANGIOGRAM: QUESTIONABLE FOCAL OCCLUSION OF THE PICA JUST LEFT OF MIDLINE. LP: NEGATIVE. TEE: PFO WITH R TO L SHUNTING (CONSULT WITH CONGENITAL HEART SPECIALIST). US LE EXTREMITIES: NEGATIVE. HYPERCOAGULABILITY LABS:	System	11 Jun 2021 14:45:08

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[Narrative](#)

Audit	User	Time (GMT)
NO SUGGESTION OF CURRENT HYPERCOAGULABLE STATE. DX: CRYPTOGENIC STROKE: "CRYPTOGENIC STROKE WITH ECHOCARDIOGRAM RESULTS REVIEWED EXTENSIVELY, POINTING TO A PROMINENT PFO GIVEN TECHNICAL LIMITATIONS OF THE TEE. GIVEN HER AGE, STROKE THAT CANNOT COMPLETELY EXCLUDE PARADOXICAL/EMBOLIC ETIOLOGY, AND A PFO WITH CONCERNING FEATURES - CONSENSUS AGREEMENT MADE TO CLOSE PFO. IN ADDITION, HER PRIOR COVID STATUS INTRODUCES POSSIBLE CONCERN FOR A TRANSIENT PROTHROMBOTIC STATE GIVEN THAT IT WAS ONLY 2 MONTHS AGO. " ON 12/7/20 PT UNDERWENT CLOSURE OF PFO AND WAS DISCHARGED.' (WR#5445128)		
User closed query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to either Safety_Moderna@iqvia.com or faxed to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 17:20:27
Query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to either Safety_Moderna@iqvia.com or faxed to 866.599.1342.' answered with 'Information redacted and sent.' (Site from Safety).	Jiamin Li (b) (4)	26 Feb 2021 15:14:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:13:59

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = UNDERWENT CLOSURE OF PFO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 17:13:08
User closed query 'Per DM CLR: Narrative = PFO WITH R TO L SHUNTING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		12 Feb 2021 17:12:43
User closed query 'Per DM CLR: Narrative = HYPERCOAGULABILITY LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Feb 2021 17:12:20
User closed query 'Per DM CLR: Narrative = ANGIOGRAM, TEE PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Feb 2021 17:11:57
User closed query 'Per DM CLR: Narrative = BLOODWORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		12 Feb 2021 17:11:29
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'Already recorded on 12/7/2020.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	10 Feb 2021 21:41:41
Query 'Per DM CLR: Narrative = UNDERWENT CLOSURE OF PFO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	10 Feb 2021 21:40:27

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = PFO WITH R TO L SHUNTING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This would not be a separate AE because it is a complication of this event. ' (Site from DM).	Jiamin Li (b) (4)	10 Feb 2021 21:40:13
Query 'Per DM CLR: Narrative = HYPERCOAGULABILITY LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	10 Feb 2021 21:39:28
Query 'Per DM CLR: Narrative = ANGIOGRAM, TEE PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'MRA recorded on 12/4/2020. TEE recorded on 12/4/2020.' (Site from DM).	Jiamin Li (b) (4)	10 Feb 2021 21:39:09
Query 'Per DM CLR: Narrative = BLOODWORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	10 Feb 2021 21:37:38
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:56
User opened query 'Per DM CLR: Narrative = UNDERWENT CLOSURE OF PFO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:50
User opened query 'Per DM CLR: Narrative = PFO WITH R TO L SHUNTING. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:44

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = HYPERCOAGULABILITY LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:38
User opened query 'Per DM CLR: Narrative = ANGIOGRAM, TEE PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:33
User opened query 'Per DM CLR: Narrative = BLOODWORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 02:38:17
User opened query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to either Safety_Moderna@iqvia.com or faxed to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:03:11
User closed query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:12:24
Query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'All records have been given to study monitor through our online research binder. Please indicate if you would like for the files to be sent separately to the email or faxed.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	26 Jan 2021 14:41:50

US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. Information can be sent with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:10:36
User closed query 'PV Query: Please confirm serious criteria. It was reported that the subject was admitted to neuro ICU on 04 Dec 2020 and discharged on 07 Dec 2020. Please update as applicable. ' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:24:15
User closed query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. ' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:24:13
Query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. ' answered with 'Information given to monitor.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	24 Dec 2020 18:06:14
Query 'PV Query: Please confirm serious criteria. It was reported that the subject was admitted to neuro ICU on 04 Dec 2020 and discharged on 07 Dec 2020. Please update as applicable. ' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	24 Dec 2020 18:06:03
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:17:58
User opened query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 13:18:10
User opened query 'PV Query: Please confirm serious criteria. It was reported that the subject was admitted to neuro ICU on 04 Dec 2020 and discharged on 07 Dec 2020. Please update as applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 13:17:45



US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional treatment provided or treatment plan for the event. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:38:52
User closed query 'PV Query: Please confirm the meaning of "report in care everywhere".' (Site from Safety).		18 Dec 2020 16:38:49
User closed query 'PV Query: Please provide the date the subject saw the neurologist.' (Site from Safety).		18 Dec 2020 16:38:46
User closed query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so.' (Site from Safety).		18 Dec 2020 16:38:43
User closed query 'PV Query: Please provide date performed and results of echocardiogram with bubble study.' (Site from Safety).		18 Dec 2020 16:38:40
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		18 Dec 2020 16:38:37
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		18 Dec 2020 16:38:33
Query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so.' answered with 'Records given to monitor. ' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:49:10
Query 'PV Query: Please provide date performed and results of echocardiogram with bubble study.' answered with 'Information entered into concomitant procedures' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:49:01
Query 'PV Query: Please provide any additional treatment provided or treatment plan for the event. If none, please state so.' answered with 'All information provided in this updated narrative.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:51:10

US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the meaning of "report in care everywhere".' answered with 'This is a section of our EPIC system, irrelevant to narrative. ' (Site from Safety).	Jiamin Li (b) (4)	17 Dec 2020 21:50:48
Query 'PV Query: Please provide the date the subject saw the neurologist.' answered with 'Date provided in narrative.' (Site from Safety).	Jiamin Li (b) (4)	17 Dec 2020 21:50:34
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Not done during this admission. ' (Site from Safety).	Jiamin Li (b) (4)	17 Dec 2020 21:50:25

US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant in Cove mRNA-1273-P301 received injection #1 on 9/25/20. Prior to receiving injection #2 she developed COVID sx. Tested at outside facility on 10/26/20, COVID was confirmed as per study procedure on 10/27/20. Covid clinical course was uneventful, not requiring ER or MD visit, sx were mild-moderate.  Patient was seen in ED on Monday 11/30 after she acutely developed nausea/vomiting and difficulty walking due to the sensation of beong pulled to one side. She was given Zofran x 1 dose in ED and was sent home on meclizine 25 mg PO twice daily with a presumed dx of vertigo Her symptoms were improving but she continued to have some vertigo with associated headache and nausea.  She saw a neurologist on 12/2/20 who did bloodwork and her CBC and CRP levels were normal. The working diagnosis at that time was vestibular neuritis but she is scheduled for an MRI on 12/4 to rule out other conditions.   12/4/20 MRI: Acute left PICA territory infarct mass effect on the fourth ventricle MRA H/N-unremarkable  12/4/20: pt obtained a second opinion and was admitted to Mt Sinai/Brooklyn to the neuro ICU. Pt was unblinded per protocol and angiogram, LP, TEE performed.  Angiogram: questionable focal occlusion of the PICA just left of midline. LP: negative. TEE: PFO with R to L shunting (Consult with congenital heart specialist). US LE extremities: negative. Hypercoagulability labs: no suggestion of current hypercoagulable state.  DX: CRYPTOGENIC STROKE: "Cryptogenic stroke with echocardiogram results reviewed extensively, pointing to a prominent PFO given technical limitations of the TEE. Given her age, stroke that cannot completely exclude paradoxical/embolic etiology, and a PFO with concerning features - consensus agreement made to close PFO. In addition, her prior COVID status introduces possible concern for a transient prothrombotic state given that it was	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:50:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
only 2 months ago. "  on 12/7/20 pt underwent closure of PFO and was discharged.'		
reason for change: Data Entry Error		
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'No medical history.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 21:36:55
User opened query 'PV Query: Please provide any additional treatment provided or treatment plan for the event. If none, please state so.' (Site from Safety)	(b) (4), (b) (6)	11 Dec 2020 18:03:11
User opened query 'PV Query: Please confirm the meaning of "report in care everywhere".' (Site from Safety).		11 Dec 2020 18:01:59
User opened query 'PV Query: Please provide the date the subject saw the neurologist.' (Site from Safety).		11 Dec 2020 18:01:26
User opened query 'PV Query: Please provide laboratory testing and or diagnostic testing with results performed in the Emergency Department on 30 Nov 2020. If none or not available, please state so.' (Site from Safety).		11 Dec 2020 18:01:13
User opened query 'PV Query: Please provide date performed and results of echocardiogram with bubbl study.' (Site from Safety).		11 Dec 2020 17:58:27
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		11 Dec 2020 17:57:07
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		11 Dec 2020 17:56:31

US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant received injection 9/25. Developed COVID on 10/26.  Patient was seen in ED on Monday 11/30 after she acutely developed vertigo. She had typical sympoms of vertigo including nausea/vomiting and difficulty walking due to the sensation of beong pulled to one side. She was given Zofran/Reglan x 1 dose in ED and discharged.  She was sent him meclizine 25 mg PO BID which she is still taking. Her symptoms are improving but she continues to have some vertigo with associated headache and nausea,  She saw a neurologist who did bloodwork and her CBC and CRP levels were normal. The working diagnsois is vestibular neuritis but she is scheduled for an MRI to rule out other conditions.   Spoke with patient who had MRI/MRA today. Report in Care everywhere.  An acute stroke explains her vertigo. Acute left PICA territory infarct mass effect on the fourth ventricle  as described. Findings discussed with Dr. (b) (6) at the time of this  dictation, with read back procedure MRA normal.  She will have a ECHO with bubble study and labs were sent to evaluate for other etiologies. Differential also includes: COVID-related (1 mo ago)m vaccine-related (2mos ago) or other etiology (as mentioned work up pending).' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:37:28

US3652038

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:01:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient was seen in ED on Monday 11/30 after she acutely developed vertigo. She had typical symptoms of vertigo including nausea/vomiting and difficulty walking due to the sensation of being pulled to one side. She was given Zofran/Reglan x 1 dose in ED and discharged. She was sent him meclizine 25 mg PO BID which she is still taking. Her symptoms are improving but she continues to have some vertigo with associated headache and nausea.  She saw a neurologist who did bloodwork and her CBC and CRP levels were normal. The working diagnosis is vestibular neuritis but she is scheduled for an MRI to rule out other conditions.   No indication this relates to vaccine - neurologist is uncertain if could relate to COVID, although her infection was approx a month prior. She will keep study team informed of results.'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:27:51

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 22:27:51

**US3652038**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 22:27:51



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 15:01:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:14:38
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:06
User entered 'Yes (Y)'	Jiamin Li (b) (4)	25 Sep 2020 19:20:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTS YNOM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:54:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:54:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: MINERALS NOS; VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:54:50
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 Sep 2020 10:54:50
Data point term sent to Coder	System	25 Sep 2020 19:21:21
User entered 'Multiple vitamins - minerals'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Supplement'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'I'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'tablet (TABLET)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'un Jan 2019'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:38



**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:20:38

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:20:38

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 19:20:38

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:59:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 13:59:18
Data point term sent to Coder Coding entries removed.	System Jiamin Li (b) (4)	26 Jan 2021 14:45:20 26 Jan 2021 14:45:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:16:20
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 07:21:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 07:21:06
Data point term sent to Coder Coding entries removed.	System Jiamin Li (b) (4)	01 Dec 2020 03:00:48 01 Dec 2020 03:00:05

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
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)	06 Oct 2020 21:12:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 21:12:27
Data point term sent to Coder	System	06 Oct 2020 21:11:42
User entered 'ibuprofen'	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE LEFT ARM is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE LEFT ARM did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:14:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE LEFT ARM is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE LEFT ARM did not meet the AE reporting criteria.' answered with 'Solicited event that occurred within 7 days of IP. Does not meet AE reporting criteria.' (Site from DM).	Jiamin Li (b) (4)	25 Apr 2021 18:02:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:37

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE LEFT ARM is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE LEFT ARM did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:06:54
User closed query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN RELIEVER (EDIARY SYMPTOMS). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:22:55
Query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN RELIEVER (EDIARY SYMPTOMS). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:45:05
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:45:02
User entered 'Pain at injection site left arm (EDIARY SYMPTOMS)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:45:02
User opened query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN RELIEVER (EDIARY SYMPTOMS). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:29:18
User closed query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' (Site from DM).		21 Dec 2020 04:29:16
Query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' answered with 'Not reportable ' (Site from DM).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:00:24
Query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' answered with 'Not reportable ' (Site from DM).	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:00:23
User opened query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 17:55:29
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' (Site from DM).		02 Dec 2020 17:55:29
User opened query 'Per CDM Re-Query: Please note that some SAR might be entered as AEs when they met reportable criteria. Please confirm if this was the case as per Protocol section 8.3.4. Thank you' (Site from DM).		02 Dec 2020 17:55:23

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 17:55:23
User entered 'PAIN RELIEVER (eDiary symptoms)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 03:00:05
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Pain symptoms derived from eDiary. Not reportable per protocol.' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:59:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' answered with 'Pain symptoms derived from eDiary. Not reportable per protocol.' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:59:55
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 11:53:25

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:07:20
User entered 'Pain Reliever'	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '400'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'twice daily (BID)' reason for change:	Jiamin Li (b) (4)	01 Dec 2020 02:59:35
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
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)	02 Dec 2020 08:41:53
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)	01 Dec 2020 02:59:40
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:59:35
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 08:59:00
User entered 'twice'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '26 Sep 2020'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '26 Sep 2020'	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:14:42
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:24:03
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' answered with 'updated' (Site from DM).	Jiamin Li (b) (4)	25 Apr 2021 18:02:44
DataPoint Un-verified.	Jiamin Li (b) (4)	25 Apr 2021 18:02:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Apr 2021 18:02:30
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
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).	(b) (4), (b) (6)	02 Dec 2020 08:41:16
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 'Not solicited per protocol definition since eDiary symptoms did not last past 7 days of drug administration' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:59:33

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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)	06 Nov 2020 09:08:57
	Genessi Rodriguez (b) (4)	06 Oct 2020 21:10:56
	(b) (4)	



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '2'	System	01 Dec 2020 02:59:35
User entered empty.	System	06 Oct 2020 21:10:56

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '1'	System	01 Dec 2020 02:59:35
User entered empty.	System	06 Oct 2020 21:10:56

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:19
User entered '804 (804)'	System	01 Dec 2020 02:59:35
User entered empty.	System	06 Oct 2020 21:10:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 00:16:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 00:16:39
Data point term sent to Coder	System	04 Dec 2020 22:36:37
User entered 'Reglan'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'PICA Territory Infarct Mass Effect'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Unknown'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Unknown'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '30 Nov 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '30 Nov 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:35:58

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User entered empty.	System	04 Dec 2020 22:35:58

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User entered empty.	System	04 Dec 2020 22:35:58

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:20
User entered empty.	System	04 Dec 2020 22:35:58

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:35:48
Data point term sent to Coder	System	04 Dec 2020 22:36:37
User entered 'Zofran'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'PICA Territory Infarct Mass Effect'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Unknown'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Unknown'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '30 Nov 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '30 Nov 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	04 Dec 2020 22:36:35

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User entered empty.	System	04 Dec 2020 22:36:35

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User entered empty.	System	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:01:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:25
User entered empty.	System	04 Dec 2020 22:36:35

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:07:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:07:18
Data point term sent to Coder	System	04 Dec 2020 22:37:38
User entered 'Meclizine'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
User closed query 'Re-query: Per CDM: response noted, however kindly confirm the indication name.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:08:00
Query 'Re-query: Per CDM: response noted, however kindly confirm the indication name.' answered with 'Confirmed indication name is correct.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	11 Feb 2021 16:25:37
User opened query 'Re-query: Per CDM: response noted, however kindly confirm the indication name.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:26:25
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:26:25
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Meclizine was used for dizziness/vertigo (which was the initial symptom of the pt's stroke prior to diagnosis). ' (Site from DM).	Jiamin Li (b) (4) (b) (4)	04 Feb 2021 15:42:56
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:34:19
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'PICA Territory Infarct Mass Effect'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '25'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'twice daily (BID)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '01 Dec 2020'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:36:56

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 22:36:56

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 22:36:56



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 22:36:56

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:09:37
Data point term sent to Coder	System	17 Dec 2020 22:11:41
User entered 'Ondansetron'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
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).	(b) (4), (b) (6)	27 Jan 2021 08:23:25
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 'The AE is entered as cryptogenic stroke' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:46:24
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 02:38:25
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Nausea and vomiting (related to cryptogenic stroke)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '4'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'as needed (PRN)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '30 Nov 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '04 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:10:44



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User entered empty.	System	17 Dec 2020 22:10:44

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User entered empty.	System	17 Dec 2020 22:10:44

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:30
User entered empty.	System	17 Dec 2020 22:10:44

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:12:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:12:44
Data point term sent to Coder	System	17 Dec 2020 22:11:41
User entered 'Atorvastatin'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Stroke Prevention'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '80'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '05 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:11:11

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User entered '1'	System	17 Dec 2020 22:11:11

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User entered '1'	System	17 Dec 2020 22:11:11

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:31
User entered '804 (804)'	System	17 Dec 2020 22:11:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:20:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:20:51
Data point term sent to Coder	System	17 Dec 2020 22:19:44
User entered 'Apixaban'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Stroke prevention'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '5'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:01:14**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '05 Dec 2020'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:19:40

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:19:40

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:19:40

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 22:19:40

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:21:46
Data point term sent to Coder	System	17 Dec 2020 22:20:46
User entered 'Aspirin'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Stroke prevention'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '81'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:07

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:20:07

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:20:07



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 22:20:07

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:21:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:21:47
Data point term sent to Coder	System	17 Dec 2020 22:20:45
User entered 'Ferrous Sulfate'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:41
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Supplementation'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '325'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '04 Dec 2020'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:20:32



**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:20:32

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:20:32

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 22:20:32

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:22:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:22:50
Data point term sent to Coder	System	17 Dec 2020 22:21:47
User entered 'Vitamin C'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Supplementation'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '500'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once daily (QD)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Oral (ORAL)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '04 Dec 2020'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:21:10

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:21:10

**US3652038**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 22:21:10

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 22:21:10

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:32:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:32:50
Data point term sent to Coder	System	17 Dec 2020 22:30:53
User entered 'Fentanyl'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User closed query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 12 and # 13 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)	05 Feb 2021 07:28:08
Query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 12 and # 13 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 'Closure of the patent foramen ovale recorded as procedure. ' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 15:50:49
User opened query 'Per DM CLR: Please note that there is no ConProc matching Con Med # 12 and # 13 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 02:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Anesthesia for procedure related to cryptogenic stroke'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '50'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'ug (ug)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:30:27

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User entered empty.	System	17 Dec 2020 22:30:27

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User entered empty.	System	17 Dec 2020 22:30:27

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:46
User entered empty.	System	17 Dec 2020 22:30:27

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:17:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:17:47
Data point term sent to Coder	System	17 Dec 2020 22:31:54
User entered 'Midazolam'	Jiamin Li (b) (4) (b) (4)	17 Dec 2020 22:31:06



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Anesthesia for procedure related to cryptogenic stroke'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '2'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:31:06

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User entered empty.	System	17 Dec 2020 22:31:06

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User entered empty.	System	17 Dec 2020 22:31:06



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:48
User entered empty.	System	17 Dec 2020 22:31:06

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:09:37
Data point term sent to Coder	System	17 Dec 2020 22:36:02
User entered 'Ondansetron'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:33:30
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Ondanestron is used to prevent the pt from vomiting and choking during procedure. Standard medicine used during anesthesia.' (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 15:46:29
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:43:48
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Anesthesia for procedure related to cryptogenic stroke'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '4'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'mg (mg)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '07 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:35:59



US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User entered empty.	System	17 Dec 2020 22:35:59

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User entered empty.	System	17 Dec 2020 22:35:59

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:57
User entered empty.	System	17 Dec 2020 22:35:59

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:40:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:40:02
Data point term sent to Coder	System	17 Dec 2020 22:38:05
User entered 'Cefazolin'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Yes (Y)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Antibiotic prophylaxis for procedure related to cryptogenic stroke'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '2'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'g (g)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'once (ONCE)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '08 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '0'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14



US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered '08 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:01:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User signature succeeded.	Kristen Marks (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:16:20
User entered 'No (N)'	Jiamin Li (b) (4)	17 Dec 2020 22:37:14

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:01:14**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User entered empty.	System	17 Dec 2020 22:37:14

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User entered empty.	System	17 Dec 2020 22:37:14

US3652038

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:01:14**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:51:58
User entered empty.	System	17 Dec 2020 22:37:14

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 15:01:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:14:38
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:42:18
User entered 'Yes (Y)'	Jiamin Li (b) (4)	04 Dec 2020 22:31:27

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '04 Dec 2020'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:32:13

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'MRA Head Without Contrast'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:32:13



US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:32:13

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4) (b) (4)	04 Dec 2020 22:32:13

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '04 Dec 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:32:30

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'MR Brain Without Contrast'	Jiamin Li (b) (4)	04 Dec 2020 22:32:30

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	04 Dec 2020 22:32:30

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:20
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:32:30

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '04 Dec 2020'	Jiamin Li (b) (4)	04 Dec 2020 22:32:49

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'MRA Neck Without Contrast'	Jiamin Li (b) (4)	04 Dec 2020 22:32:49



US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	04 Dec 2020 22:32:49

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:23
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	04 Dec 2020 22:32:49

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '05 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:46:51

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Lumbar Puncture'	Jiamin Li (b) (4)	17 Dec 2020 22:46:51

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	17 Dec 2020 22:46:51

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:27
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:46:51

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:37
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '05 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:47:17

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:37
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'transthoracic echocardiogram'	Jiamin Li (b) (4)	17 Dec 2020 22:47:17



US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:37
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	17 Dec 2020 22:47:17

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:37
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:47:17

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
Data entry locked.		01 May 2021 11:25:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '06 Dec 2020'	Jiamin Li (b) (4)	17 Dec 2020 22:47:45

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
Data entry locked.		01 May 2021 11:25:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Doppler Ultrasound (Lower Extremity)'	Jiamin Li (b) (4)	17 Dec 2020 22:47:45
	(b) (4)	

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
Data entry locked.		01 May 2021 11:25:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	17 Dec 2020 22:47:45
	(b) (4)	

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:25:59
Data entry locked.		01 May 2021 11:25:51
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	17 Dec 2020 22:47:45
	(b) (4)	

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '07 Dec 2020'	Jiamin Li (b) (4)	04 Feb 2021 15:50:27

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Closure of the patent foramen ovale'	Jiamin Li (b) (4)	04 Feb 2021 15:50:27



US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	04 Feb 2021 15:50:27

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:09
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	04 Feb 2021 15:50:27

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '02 Dec 2020'	Jiamin Li (b) (4)	10 Feb 2021 21:37:28

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Bloodwork'	Jiamin Li (b) (4)	10 Feb 2021 21:37:28

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	10 Feb 2021 21:37:28

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:24
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	10 Feb 2021 21:37:28

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:01:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered '04 Dec 2020'	Jiamin Li (b) (4)	10 Feb 2021 21:39:41

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:01:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'HYPERCOAGULABILITY LABS.'	Jiamin Li (b) (4)	10 Feb 2021 21:39:41



US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:01:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	10 Feb 2021 21:39:41

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 11 Jun 2021 15:01:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:26:28
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:59
User entered empty.	Jiamin Li (b) (4)	10 Feb 2021 21:39:41

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:15:44
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:06:16
User entered '24 Oct 2020'	Jiamin Li (b) (4)	25 Nov 2020 16:54:52

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:15:44
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:19
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:28:47
User closed query 'Per CDM re-query: Thank you for the update. Please consider to record the AE log line number on "specify" field.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 06:19:24
Query 'Per CDM re-query: Thank you for the update. Please consider to record the AE log line number on "specify" field.' answered with 'Per previous CDM query: "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)." (Site from DM).	Jiamin Li (b) (4)	04 Feb 2021 15:48:40
User opened query 'Per CDM re-query: Thank you for the update. Please consider to record the AE log line number on "specify" field.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:12:03
User closed query 'Per CDM re-query: Response noted. However, as per CCG V3.0 page 47, "Mark the 'Due to SARS-COV-2' if the participant is diagnosed". So please reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:12:03
Query 'Per CDM re-query: Response noted. However, as per CCG V3.0 page 47, "Mark the 'Due to SARS-COV-2' if the participant is diagnosed". So please reconcile and update as appropriate.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	26 Jan 2021 14:51:41
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:51:38
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 14:51:38
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:06:16

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Response noted. However, as per CCG V3.0 page 47, "Mark the 'Due to SARS-COV-2' if the participant is diagnosed". So please reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:01:05
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)	28 Dec 2020 05:01:05
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 'Reason was originally cited as due to SARS-COV-2, but we received a request for this to be changed to AE. ' (Site from DM).	Jiamin Li (b) (4) (b) (4)	24 Dec 2020 18:12:57
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 05:34:46
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	01 Dec 2020 02:58:06
User entered 'Due to SARS-COV-2 (COVID)'	Jiamin Li (b) (4) (b) (4)	25 Nov 2020 16:54:52

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

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 03:15:44
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:43:19
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 07:34:25
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Mar 2021 16:44:00
User entered 'AE #2' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Mar 2021 16:43:57
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	(2128 03 Mar 2021 14:11:34
Query 'Per CDM:RQ: Response noted. Please consider to remove AE term from specify field and keep only AE log line no. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	(2128 03 Mar 2021 14:11:27
User opened query 'Per CDM:RQ: Response noted. Please consider to remove AE term from specify field and keep only AE log line no. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:29:41
User closed query 'Per CDM: Response provided as updated however AE log line no. is still not updated in specify field. Please consider to record it. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:33:05
Query 'Per CDM: Response provided as updated however AE log line no. is still not updated in specify field. Please consider to record it. Thank you' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	11 Feb 2021 16:29:12

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
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	11 Feb 2021 16:29:09
User entered 'COVID-19 (AE log line 2)' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Feb 2021 16:29:09
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).	(b) (4)	
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	11 Feb 2021 16:28:47
User opened query 'Per CDM: Response provided as updated however AE log line no. is still not updated in specify field. Please consider to record it. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:34:52
DataPoint Un-verified.	Jiamin Li (b) (4)	26 Jan 2021 14:51:38
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Verified.	Jiamin Li (b) (4)	26 Jan 2021 14:51:38
	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 21:06:16
User closed query 'Per CDM: Please record AE record number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:34:51
Query 'Per CDM: Please record AE record number. Thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Dec 2020 02:58:30
	(b) (4)	
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 02:58:26
User entered 'AE# 2' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Dec 2020 02:58:26
	(b) (4)	
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 02:58:06
User opened query 'Per CDM: Please record AE record number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 10:58:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2334 of 2547

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:01:14

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Nov 2020 16:54:52



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29



**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
User entered '04/Nov/2020 15:28'	System	04 Nov 2020 15:28:29

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:28:29

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
User entered '17/Nov/2020 18:12'	System	17 Nov 2020 18:12:41

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:49:39
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 18:12:41

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
User entered '20/Nov/2020 23:50'	System	20 Nov 2020 23:50:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:33:47
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 23:50:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
User entered '25/Nov/2020 09:33'	System	25 Nov 2020 14:34:00

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 14:34:00



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'USA-US132-2020-MRNA-1273-P301000001'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:49
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
Un-reviewed for Safety.	System	05 Dec 2020 19:07:20
User entered 'No (N)'	System	05 Dec 2020 19:07:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:31:39
Un-reviewed for Safety.	System	05 Dec 2020 18:29:46
DataPoint Un-verified.	System	05 Dec 2020 18:29:46
User entered 'Yes (Y)'	System	05 Dec 2020 18:29:46
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'No (N)'	System	04 Nov 2020 15:27:30



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Kristen'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'Marks'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '525 East 68th Street'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'New York'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered 'NY'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:28:15
User entered '10065'	System	04 Nov 2020 15:27:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 15:10:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered 'US'	System	04 Nov 2020 15:28:29

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	05 Dec 2020 18:32:25
User entered '4'	System	25 Nov 2020 14:34:00
User entered '3'	System	20 Nov 2020 23:50:20
User entered '2'	System	17 Nov 2020 18:12:41
User entered '1'	System	04 Nov 2020 15:28:29



**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
User entered '05/Dec/2020 12:32'	System	05 Dec 2020 18:32:25

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:38:21
User entered '0' reason for change: Data Entry Error		05 Dec 2020 19:19:03
User entered '1' reason for change: Data Entry Error		05 Dec 2020 19:10:14
User entered '0' reason for change: Data Entry Error		05 Dec 2020 19:09:52
User entered '1'		05 Dec 2020 18:32:25

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
User entered '05/Dec/2020 19:18'	System	05 Dec 2020 19:18:38

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 16:40:40
User entered 'I'	(b) (4), (b) (6)	05 Dec 2020 19:18:38

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
User entered '18/Dec/2020 16:40'	System	18 Dec 2020 16:40:52

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 16:40:52

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
User entered '28/Dec/2020 20:24'	System	28 Dec 2020 20:24:55

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:25:32
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 20:24:55



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38



**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
User entered '28/Jan/2021 14:25'	System	28 Jan 2021 14:25:44

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:01:14

**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)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:37:10
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 14:25:44

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'USA-US132-2020-MRNA-1273-P301000003'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:45:30
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:24:43
Un-reviewed for Safety.	System	24 Dec 2020 18:03:57
DataPoint Un-verified.	System	24 Dec 2020 18:03:57
User entered 'Yes (Y)'	System	24 Dec 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'No (N)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Yes (Y)'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Kristen'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'Marks'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '525 East 68th Street'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'New York'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'NY'	System	05 Dec 2020 19:07:20

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered '10065'	System	05 Dec 2020 19:07:20



US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Jun 2021 15:01:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	16 Apr 2021 12:59:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 20:48:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 19:18:29
User entered 'US'	System	05 Dec 2020 19:10:14

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:01:14**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:37:30
User entered '4'	System	28 Jan 2021 14:25:44
User entered '3'	System	28 Dec 2020 20:24:55
User entered '2'	System	18 Dec 2020 16:40:52
User entered '1'	System	05 Dec 2020 19:18:38

**US3652038**

**Folder: SAE USA-US132-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 11 Jun 2021 15:01:14**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kristen Marks (b) (4) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:25:40
User entered '26/Apr/2021 11:37'	System	26 Apr 2021 15:37:30

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 15:01:14

**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) (b) (4)	28 Apr 2021 22:28:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 06:25:40
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 15:37:30