

US3652038 (Prod: Weill Cornell Medical College)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:09:28

All time stamps listed in this document are displayed in GMT

US3652038

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:28

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:28

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
BMI (<i>xxx.x</i>)	
BMI units	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐	No ☒
Other	Yes ☐	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	TAKES PUBLIC TRANSPORTATION FREQUENTLY

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Height	162.6 cm
Weight	54.9 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

Height	162.6 cm
Weight	54.9 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:09:28

Height	162.6 cm
Weight	54.9 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Was the sample collected?	Yes ☒
	No ☐
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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:28

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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 ☒

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

Yes ☐	
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: 26 Nov 2020 11:09:28

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 ☒

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

Yes ☐	
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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

Yes ☐	
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: 26 Nov 2020 11:09:28

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 ☐

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:28

	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: 26 Nov 2020 11:09:28

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 ☒

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:28

Yes ☐	
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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

	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

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3652038

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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 _____

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3652038

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Was the pregnancy test performed?	Yes ☐
	No ☐
Date of test (<i>dd MMM yyyy</i>)	
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

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

Was the sample collected?	Yes ☐
	No ☐

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

US3652038

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:28

Collection date (<i>dd MMM yyyy</i>)			
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3652038

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 103

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 145

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

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11 MAR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

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18 MAR 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 187

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:09:28

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 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: 26 Nov 2020 11:09:28

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:09:28

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 327

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 341

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 439

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 530

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 600

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

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

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

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

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

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 621

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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15 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 726

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

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22 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 733

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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25 SEP 2022 00:01

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29 SEP 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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06 OCT 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 747

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

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

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

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

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

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

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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09 OCT 2022 00:01

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13 OCT 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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16 OCT 2022 00:01

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20 OCT 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

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27 OCT 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

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03 NOV 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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06 NOV 2022 00:01

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10 NOV 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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13 NOV 2022 00:01

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17 NOV 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

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

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

Date and time of submission

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20 NOV 2022 00:01

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24 NOV 2022 23:59

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:28

Date of Contact	27 OCT 2020
Time of Contact	13:20
Date and Time of Contact (derived)	27 OCT 2020 13:20
Type of Contact	Clinic Visit - Scheduled ☒
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	285 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	289 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	293 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.6 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	297 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.7 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	301 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	305 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	309 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	313 of 1689	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	317 of 1689	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	321 of 1689	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	325 of 1689	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	329 of 1689	

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	333 of 1689	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	337 of 1689	

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

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 _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:28

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:09:28

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 OCT 2020
Day 5	Yes	30 OCT 2020
Day 7	Yes	02 NOV 2020
Day 9	Yes	04 NOV 2020
Day 14	Yes	09 NOV 2020
Day 21		
Day 28	Yes	24 NOV 2020

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	SICKD1

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

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.

US3652038

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:09:28

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	355 of 1689

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

AEID	USA-US132-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	25 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	06 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	357 of 1689

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

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)	

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:28

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

Yes ☒

No ☐

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

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:28

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 ☐ Intraocular ☐

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:28

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:28

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN RELIEVER
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:28

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3652038

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:28

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3652038

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:28

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3652038

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:28

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

Generated On: 26 Nov 2020 11:09:28

SAEID	USA-US132-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:28

SAEID	USA-US132-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
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)

Generated On: 26 Nov 2020 11:09:28

SAEID	USA-US132-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
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)

Generated On: 26 Nov 2020 11:09:28

SAEID	USA-US132-2020-MRNA-1273-P301000001
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
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

Audit

US3652038 (Prod: Weill Cornell Medical College)

US3652038

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:28

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3652038'	RWS_ENDPOINT ENDPOINT (b) (4) 	25 Sep 2020 11:34:08

US3652038

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:30:55
User entered 'Home (Home)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:05

US3652038

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	25 Sep 2020 12:58:05

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '34'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '34'	System	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

Sex

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered 'Female (F)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '1'	Ashley Machado (b) (4)	25 Sep 2020 12:58:36
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Black](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Asian](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:02
User entered '0'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:36

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Other](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[If race is Other, specify](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

Unknown

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:28

[Not reported](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'Amendment 3 (3)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'Yes (Y)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered empty.	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered empty.	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:06
User entered 'No (N)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 12:58:59

US3652038

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:11
User entered 'Yes (Y)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:13:16

US3652038

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:16
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:49

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:21
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:19:54

US3652038

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:27
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:59

US3652038

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:27
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:59

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '24 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

If No, what is the reason?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:28

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:33
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:18:20

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:46
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:20:05

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

No Risk Identified

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:51
User entered '0'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	25 Sep 2020 19:22:55
User entered '0'	(b) (4) Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:19:08

US3652038

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:28

[Specify](#)

Audit	User	Time (GMT)
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)	

US3652038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered 'Yes (Y)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:13:44

US3652038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered '25 Sep 2020'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:13:44

US3652038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:31:58
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:13:44

US3652038

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	25 Sep 2020 13:13:44

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:09

US3652038

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '25 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '08:48'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 08:48'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '36.3' C	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Oral (Oral)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '84'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '17'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '99'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '66'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '162.6' cm	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:28

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '54.9' kg	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '25 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '10:26'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 10:26'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '36.6' C	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered 'Oral (Oral)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '76'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '17'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '102'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:14
User entered '68'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 19:22:11

US3652038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:18
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:31

US3652038

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:18
User entered '25 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:22:31

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered '25 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Urine (URINE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'Negative (NEGATIVE)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:22
User entered empty.	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:23:26

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered 'Yes (Y)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

[If No, reason not given](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered empty.	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 9:53'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:26
User entered 'Left Arm (LEFT ARM)'	Ashley Machado (b) (4) (b) (4)	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 13:54:57

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered '25 Sep 2020'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:30
User entered '09:21'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 09:21'	System	25 Sep 2020 19:24:09

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:28

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered '09:25'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered 'No (N)'	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: 26 Nov 2020 11:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:32:34
User entered empty.	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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:23:38

US3652038

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:23:44

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:01
User entered 'Yes (Y)'	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:01
User entered '97.9'	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:01
User entered 'No (N)'	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:01
User entered '25 Sep 2020 10:28'	System	25 Sep 2020 14:29:01

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-ac9f0bceda54'	System	25 Sep 2020 23:21:55
User entered 'Yes (Y)'	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-ac9f0bceda54'	System	25 Sep 2020 23:21:55
User entered '97.6'	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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-ac9f0bceda54'	System	25 Sep 2020 23:21:55
User entered 'No (N)'	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-ac9f0bceda54'	System	25 Sep 2020 23:21:55
User entered '25 Sep 2020 19:21'	System	25 Sep 2020 23:21:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:10:52
User entered '97.7'	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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). 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'	System	26 Sep 2020 23:10:52
User entered '1'	System	26 Sep 2020 23:10:52

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:14:55
User entered 'Yes (Y)'	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:14:55
User entered '96.4'	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:14:55
User entered 'No (N)'	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:14:55
User entered '27 Sep 2020 21:14'	System	28 Sep 2020 01:14:55

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:07
User entered 'Yes (Y)'	System	29 Sep 2020 02:55:07

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:07
User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:07

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	01 Oct 2020 01:45:16
User entered 'Yes (Y)'	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	01 Oct 2020 01:45:16
User entered '97.2'	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	01 Oct 2020 01:45:16
User entered '30 Sep 2020 21:45'	System	01 Oct 2020 01:45:16

US3652038

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:31
User entered 'No (N)'	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:31
User entered 'No (N)'	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:31
User entered '25 Sep 2020 10:29'	System	25 Sep 2020 14:29:31

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:22:54
User entered 'No (N)'	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:22:54
User entered 'No (N)'	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:22:54
User entered '25 Sep 2020 19:22'	System	25 Sep 2020 23:22:54

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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' 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: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:11:41
User entered 'No (N)'	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:11:41
User entered 'No (N)'	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:11:41
User entered '26 Sep 2020 19:11'	System	26 Sep 2020 23:11:41

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:21
User entered 'No (N)'	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:21
User entered 'No (N)'	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:21
User entered 'None (1)'	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:21
User entered '27 Sep 2020 21:15'	System	28 Sep 2020 01:15:21

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:24
User entered 'None (1)'	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:24
User entered 'None (1)'	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:24
User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:24

US3652038

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:09:28

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:53
User entered 'None (0)'	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:53
User entered 'None (0)'	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 14:29:53
User entered 'No (N)'	System	25 Sep 2020 14:29:53

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'None (0)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered 'No (N)'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 23:23:18
User entered '25 Sep 2020 19:23'	System	25 Sep 2020 23:23:18

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:12:07
User entered 'None (0)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:12:07
User entered 'None (0)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:12:07
User entered 'None (0)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:12:07
User entered 'No (N)'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 23:12:07
User entered '26 Sep 2020 19:12'	System	26 Sep 2020 23:12:07

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'None (0)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered 'No (N)'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 01:15:36
User entered '27 Sep 2020 21:15'	System	28 Sep 2020 01:15:36

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'None (0)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered 'No (N)'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 02:55:38
User entered '28 Sep 2020 22:55'	System	29 Sep 2020 02:55:38

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	01 Oct 2020 01:45:39
User entered 'None (0)'	System	01 Oct 2020 01:45:39

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:28

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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

US3652038

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered '05 Oct 2020'	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered 'Contact Made (CONTACT MADE)'	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:45
User entered empty.	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 20:57:42

US3652038

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:49
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4) (b) (4)	06 Oct 2020 20:56:53

US3652038

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 20:56:53

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered '09 Oct 2020'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:54
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:38

US3652038

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:33:58
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:43

US3652038

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 02:52:43

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered '16 Oct 2020'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:04
User entered empty.	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:53:40

US3652038

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:34:08
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:53:45

US3652038

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 02:53:45

US3652038

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:28

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:28

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered '13:20'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:28

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:28

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:52:34
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:07:42

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:23:32
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:19:25
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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 '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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 '98.3' 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: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:09:08

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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 (3)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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.	System	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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 '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: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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 'Mild (Mild)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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 'None (None)'	Jiamin Li (b) (4)	02 Nov 2020 17:10:57

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:23:42
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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 '28 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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 '36.6' C	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:20:21

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:23:52
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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 '29 Oct 2020'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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 '36.7' C	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:24:36

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:24:01
User entered 'Day 4 (Day 4)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:27:31

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:24:09
User entered 'Day 5 (Day 5)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 17:29:41

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:24:17
User entered 'Day 6 (Day 6)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	02 Nov 2020 22:21:13

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Jiamin Li (b) (4) (b) (4)	05 Nov 2020 21:45:15

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	05 Nov 2020 21:45:15

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Jiamin Li (b) (4) (b) (4)	06 Nov 2020 12:51:45

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:51:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:13:19

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:31:30

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
User entered '08 Nov 2020'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:32:38

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Date](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.1' F	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:28

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jiamin Li (b) (4) (b) (4)	13 Nov 2020 21:33:45

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:28

[Date of Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:28

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Date of Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:28

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:07
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:28

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
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

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
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

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[CLIA Certified?](#)

Audit	User	Time (GMT)
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

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 17:12:56

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

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Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Folder: Covid-19 Assessment 27 Oct 2020

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Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

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Form: Covid-19 Severity Assessment

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (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)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:28

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:14:48

US3652038

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:28

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:24
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	02 Nov 2020 17:15:24

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jiamin Li (b) (4)	19 Nov 2020 18:34:58
	(b) (4)	
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	19 Nov 2020 18:34:58
	(b) (4)	
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
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:53:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (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) (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) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
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.	(b) (4)	
	Jiamin Li (b) (4)	03 Nov 2020 15:47:37
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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) (b) (4)	06 Nov 2020 12:53:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (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) (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) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
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.	(b) (4)	
	Jiamin Li (b) (4)	03 Nov 2020 15:47:37
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4)	
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
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:54:51
	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered with 'Not yet completed' (Site from System).	Jiamin Li (b) (4)	03 Nov 2020 15:48:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:47:37
	System	
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Nov 2020 15:42:10
	(b) (4)	
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
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
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).	(b) (4)	
	System	03 Nov 2020 15:47:37
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:47:37
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:47:37

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:28

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Ashley Machado (b) (4)	24 Nov 2020 15:05:39
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Machado (b) (4)	24 Nov 2020 15:05:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:41
	(b) (4), (b) (6)	
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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

US3652038

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Ashley Machado (b) (4)	24 Nov 2020 15:05:27
	(b) (4)	
User entered '24 Nov 2020' reason for change: Data Entry Error	Ashley Machado (b) (4)	24 Nov 2020 15:05:27
	(b) (4)	
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
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:55
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:53:55
User entered '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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).	(b) (4)	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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).	(b) (4)	03 Nov 2020 15:36:18
User entered empty.	System	03 Nov 2020 15:36:18
DataPoint set to visible.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
	(b) (4)	03 Nov 2020 15:34:06
	System	03 Nov 2020 15:34:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Weight (xxx.x)

Audit	User	Time (GMT)
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).	(b) (4)	03 Nov 2020 15:36:18
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
DataPoint set to visible.	(b) (4)	03 Nov 2020 15:34:06
	System	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '98.3' F	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
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).	(b) (4)	03 Nov 2020 15:36:18
User entered empty.	System	03 Nov 2020 15:36:18
	Jiamin Li (b) (4)	03 Nov 2020 15:36:18
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered empty.	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '74'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '98'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:04:00
User entered '70'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 15:36:18

US3652038

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:16
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:38:06

US3652038

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3652038

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:09:28

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:21
User entered 'Yes (Y)'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:54:21
User entered '27 Oct 2020'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:38:34

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Machado (b) (4) (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Ashley Machado (b) (4) (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Ashley Machado (b) (4) (b) (4)	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Nov 2020 14:40:31

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '09:35'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Height (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Weight (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '96'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '17'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '123'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '68'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 16:30:30

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:31:02

US3652038

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jiamin Li (b) (4) (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: 26 Nov 2020 11:09:28

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 16:31:42

US3652038

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 05:57:23
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:51:22

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

[Adverse event](#)

Audit	User	Time (GMT)
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)	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)	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)	22 Oct 2020 02:52:03
	(b) (4)	

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
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).	System	22 Oct 2020 02:52:03
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Oct 2020 02:52:03

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jiamin Li (b) (4) (b) (4)	22 Oct 2020 02:52:03

US3652038

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Outcome](#)

Audit	User	Time (GMT)
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)

Generated On: 26 Nov 2020 11:09:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Narrative](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[AEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Adverse event](#)

Audit	User	Time (GMT)
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.	Coder Import (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)	

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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)	16 Nov 2020 15:43:08
User entered 'No (N)' reason for change: Data Entry Error	(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)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	16 Nov 2020 15:44:06
User entered '25 Oct 2020' reason for change: Data Entry Error	(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)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[Ongoing?](#)

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)	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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Nov 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	24 Nov 2020 16:28:22
User entered empty.	Jiamin Li (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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)	16 Nov 2020 15:44:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(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)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jiamin Li (b) (4) (b) (4)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Outcome](#)

Audit	User	Time (GMT)
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)	24 Nov 2020 16:28:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (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)	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Narrative](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[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

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[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)

Generated On: 26 Nov 2020 11:09:28

[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)

Generated On: 26 Nov 2020 11:09:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 15:03:19

US3652038

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:09:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 15:03:19

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	25 Sep 2020 19:20:11

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: 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: 26 Nov 2020 11:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:09:28

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[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-STERIODS, 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: 26 Nov 2020 11:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:09:28

[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: 26 Nov 2020 11:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	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: 26 Nov 2020 11:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:09:28

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	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: 26 Nov 2020 11:09:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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

US3652038

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:09:28

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

Audit	User	Time (GMT)
User entered '26 Sep 2020'	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: 26 Nov 2020 11:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:09:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	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: 26 Nov 2020 11:09:28

[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) (b) (4)	06 Nov 2020 09:08:57
	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: 26 Nov 2020 11:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:10:56

US3652038

Folder: SAE USA-US132-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:28

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:12:26
User entered '1'	(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: 26 Nov 2020 11:09:28

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 23:49:39
User entered '1'	(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: 26 Nov 2020 11:09:28

[SAEID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Serious

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Death](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Life threatening](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Site Address: State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:09:28

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.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 23:50:20