

US3312063 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:13:42

All time stamps listed in this document are displayed in GMT

US3312063

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Participant ID

US3312063

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

US3312063

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3312063

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input checked="" type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3312063

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3312063

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312063

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Were any significant conditions reported?

Yes ☐

No ☒

US3312063

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:55
Height (xxx.x)	73 in
Weight (xxx.x)	219.2 lb
BMI (xxx.x)	28.98042 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312063

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3312063

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3312063

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103611

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 ☒

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Height	ND - Not Done
Weight	ND - Not Done

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:34
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3312063

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

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.

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:03 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:03

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

What was the frequency of the study treatment dosing? ONCE

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

US3312063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

11:19 (24 HR)

Collection date and time (derived)

13 AUG 2020 11:19

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:14	13 AUG 2020 11:14
Nasopharyngeal Swab 2	No		

US3312063

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

13 AUG 2020 12:52

PC Open Date & Time

13 AUG 2020 12:23

PC Close Date & Time

13 AUG 2020 14:53

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	13 AUG 2020 21:16
PC Open Date & Time	13 AUG 2020 15:48
PC Close Date & Time	14 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 15:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:42

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

16 AUG 2020 12:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

17 AUG 2020 17:15

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 22:31

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

19 AUG 2020 22:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

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

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

13 AUG 2020 12:54

PC Open Date & Time

13 AUG 2020 12:23

PC Close Date & Time

13 AUG 2020 14:53

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

13 AUG 2020 21:16

PC Open Date & Time

13 AUG 2020 15:48

PC Close Date & Time

14 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

14 AUG 2020 15:53

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

15 AUG 2020 19:43

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

16 AUG 2020 12:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 17:15

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

18 AUG 2020 22:31

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 22:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:55
PC Open Date & Time	13 AUG 2020 12:23
PC Close Date & Time	13 AUG 2020 14:53

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 21:17
PC Open Date & Time	13 AUG 2020 15:48
PC Close Date & Time	14 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

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 ☒

PRODUCTION RELEASE (v12.003

41 of 2196

EAB) (1725)

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 15:53
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

43 of 2196

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:44
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

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 ☒

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:34
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

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 ☒

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

		Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 17:15	
PC Open Date & Time	17 AUG 2020 12:00	
PC Close Date & Time	18 AUG 2020 11:59	

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2196

EAB) (1725)

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:32
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

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 ☒

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:01
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3312063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:13

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

N/A OCCURRED DURING
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:13

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:13

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:13

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:56
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

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 LOSS OF TASTE AND SMELL PERSISTS DESPITE NEGATIVE COVID TEST. PER PI WILL AFFECT ABILITY FOR MONITORING FOR COVID SYMPTOMS

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? _____

US3312063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

13:07 (24 HR)

Collection date and time (derived)

10 SEP 2020 13:07

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:45	10 SEP 2020 12:45
Nasopharyngeal Swab 2	No		

US3312063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:09 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 15:09
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3312063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

8 OCT 2020 15:30

US3312063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:45:14

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 08:47:55

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 12:52:40

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 OCT 2020 13:01:07
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 09:07:55
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 13:09:35

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 13:53:40
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

05 DEC 2020 18:19:23

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 07:25:26
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

21 DEC 2020 17:07:23

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 20:20:02

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 07:51:53
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 20:51:32

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 13:29:00

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:52:50

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 11:42:54

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 12:00:39

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 08:10:53

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 08:23:48

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 19:32:25

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 12:54:27

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 18:04:50
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 09:00:42

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 08:41:49

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

25 APR 2021 18:49:11

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

03 MAY 2021 12:00:30

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

Patient Cloud Open Date & Time	23 APR 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	27 APR 2022 23:59
---	-------------------

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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 ☐

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3312063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:13:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		16 MAR 2021 19:32:38

US3312063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3312063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

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.

US3312063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	19 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	08:23 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 MAR 2021 08:23
------------------------------------	-------------------

US3312063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 19:25:05

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 19:25:05

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Date of Contact	24 AUG 2020
Time of Contact	08:00
Date and Time of Contact (derived)	24 AUG 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

283 of 2196

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

295 of 2196

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

303 of 2196

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

307 of 2196

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Symptom Day

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Date of Visit	25 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	25 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

Visit date (dd MMM yyyy)	25 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
------------	--------

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	08:17 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 08:17
Height (xxx.x)	73.0 in
Weight (xxx.x)	218 lb
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3312063

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 AUG 2020

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

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.

US3312063

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312063

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3312063

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3312063

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

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

US3312063

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:46
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3312063

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3312063

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3312063

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 09:51 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 09:51

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

US3312063

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

08:32 (24 HR)

Collection date and time (derived)

22 JAN 2021 08:32

US3312063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	08:31
---------------------------------	-------

Collection Date and Time (derived)	22 JAN 2021 08:31
------------------------------------	-------------------

US3312063

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:33:17

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	OLD29

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:17 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:17
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312063

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3312063

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 FEB 2021

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

19 FEB 2021 08:36

US3312063

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:44:14

Generated On: 11 Aug 2021 22:13:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

GENERALIZED MUSCLE ACHES

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

BODY ACHES

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 AUG 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

PRODUCTION RELEASE (v12.003

346 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

NEW LOSS OF TASTE

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

348 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

NEW LOSS OF SMELL

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

350 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

RUNNY NOSE

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 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

PRODUCTION RELEASE (v12.003

352 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

VOMITING

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 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

PRODUCTION RELEASE (v12.003

356 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

DIARRHEA

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 AUG 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

PRODUCTION RELEASE (v12.003

358 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

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

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

NASAL CONGESTION

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)

21 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 AUG 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

PRODUCTION RELEASE (v12.003

364 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

AEID

Adverse event

LEFT HUMERUS FRACTURE

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)

30 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 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

PRODUCTION RELEASE (v12.003

366 of 2196

EAB) (1725)

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 12 Mar 2021 15:44:13

Generated On: 11 Aug 2021 22:13:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3312063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

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

Yes ☐

No ☒

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

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 17:33:15

Generated On: 11 Aug 2021 22:13:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 NOV 2020	SURGICAL REPAIR OF LEFT HUMERUS FRACTURE	Adverse Event	

US3312063

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 17:33:16

Generated On: 11 Aug 2021 22:13:42

Date of dosing discontinuation (dd MMM yyyy) 10 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE # 4 AND # 5

US3312063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:13:42

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 ☐

Audit

US3312063 (Prod: Johnson County Clin-Trials)

US3312063

Form: Participant Creation

Generated On: 11 Aug 2021 22:13:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'US3312063'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:10:14

US3312063

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:12:55

US3312063

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:10:16

US3312063

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	13 Aug 2020 17:12:55

US3312063

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'SCRN'	System	13 Aug 2020 17:12:55

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered (b) (6) 1976'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:10:17

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '44'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'YEARS'	System	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered '44'	System	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Unknown (UNKNOWN)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:13:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:00

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'Aug 2020'	System	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered '2020'	System	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:19

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:10:16

US3312063

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:13:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'I'	System	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:13:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:09

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10:55'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered '13 Aug 2020 10:55'	System	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '73' in	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53
DataPoint set to visible.	(b) (4) System	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '219.2' lb	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53
DataPoint set to visible.	(b) (4) System	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
Amendment Manager: User entered '28.98042'	System	16 Sep 2020 23:55:25
User entered '29.0'	System	17 Aug 2020 14:55:53
DataPoint set to visible.	System	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'kg/m2'	System	17 Aug 2020 14:55:53
DataPoint set to visible.	System	13 Aug 2020 17:13:25

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'bpm'	System	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'breaths/min'	System	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'mmHg'	System	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User entered 'mmHg'	System	17 Aug 2020 14:55:53

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39

US3312063

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39

US3312063

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:56:06

US3312063

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:57:39
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 15:50:11
User entered '13 Aug 2020'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:56:06

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '0'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'I'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:13:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:53:39
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 14:57:13

US3312063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:36

US3312063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:36

US3312063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	13 Aug 2020 17:13:36

US3312063

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'VISIT1'	System	13 Aug 2020 17:13:36

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:44:32

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:12:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:12:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:44:32
User entered '103611' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:44:32

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 16:44:32

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	Christa Estrada (b) (4)	13 Aug 2020 17:13:50

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	Christa Estrada (b) (4)	13 Aug 2020 17:13:50

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:50

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:50

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:13:50

US3312063

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:44:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:47
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:02:26

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10:55'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered '13 Aug 2020 10:55'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '98.3' F	(b) (4)	17 Aug 2020 15:00:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '87'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'bpm'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'breaths/min'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '129'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'mmHg'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'mmHg'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 12:41:55
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 15:00:31
User entered '12:34'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered '13 Aug 2020 12:34'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '98.4' F	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '70'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'bpm'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '16'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'breaths/min'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '137'	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'mmHg'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '90'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'mmHg'	System	17 Aug 2020 15:00:31

US3312063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4)	17 Aug 2020 15:00:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Aug 2020 15:00:41

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '12:03'	(b) (4) Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered '13 Aug 2020 12:03'	System	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'ONCE'	System	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:14:25

US3312063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:58

US3312063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:00:58

US3312063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '11:19'	(b) (4)	17 Aug 2020 15:00:58
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered '13 Aug 2020 11:19'	System	17 Aug 2020 15:00:58

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13 Aug 2020'	(b) (4)	17 Aug 2020 15:01:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '11:14'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered '13 Aug 2020 11:14'	System	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered empty.	System	17 Aug 2020 15:01:17

US3312063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Aug 2020 15:01:26

US3312063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'I'	System	17 Aug 2020 15:01:26

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:52:12', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2e34cd41-e99f-4ea3-824b-1b68ed2fe89d' User entered 'Yes (Y)'	System	13 Aug 2020 17:52:52
	System	13 Aug 2020 17:52:52

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:52:24', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2e34cd41-e99f-4ea3-824b-1b68ed2fe89d' User entered '98.4'	System	13 Aug 2020 17:52:52
	System	13 Aug 2020 17:52:52

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:52:36', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2e34cd41-e99f-4ea3-824b-1b68ed2fe89d'	System	13 Aug 2020 17:52:52
User entered 'No (N)'	System	13 Aug 2020 17:52:52

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:52:50', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2e34cd41-e99f-4ea3-824b-1b68ed2fe89d'	System	13 Aug 2020 17:52:52
User entered '13 Aug 2020 12:52'	System	13 Aug 2020 17:52:52

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 12:23'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 14:53'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:15:55', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e73c4b31-39e9-4979-94ac-b75f3ec9e73a' User entered 'Yes (Y)'	System	14 Aug 2020 02:16:11
	System	14 Aug 2020 02:16:11

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:02', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e73c4b31-39e9-4979-94ac-b75f3ec9e73a' User entered '98.1'	System	14 Aug 2020 02:16:11
	System	14 Aug 2020 02:16:11

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:04', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e73c4b31-39e9-4979-94ac-b75f3ec9e73a' User entered 'No (N)'	System	14 Aug 2020 02:16:11
	System	14 Aug 2020 02:16:11

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:09', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e73c4b31-39e9-4979-94ac-b75f3ec9e73a'	System	14 Aug 2020 02:16:11
User entered '13 Aug 2020 21:16'	System	14 Aug 2020 02:16:11

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 15:48'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 2'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:07', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'dae35b09-9192-428a-9065-d5ed08439ab9'	System	14 Aug 2020 20:52:33
User entered 'Yes (Y)'	System	14 Aug 2020 20:52:33

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:21', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'dae35b09-9192-428a-9065-d5ed08439ab9' User entered '98.7'	System	14 Aug 2020 20:52:33
	System	14 Aug 2020 20:52:33

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:28', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'dae35b09-9192-428a-9065-d5ed08439ab9'	System	14 Aug 2020 20:52:33
User entered 'No (N)'	System	14 Aug 2020 20:52:33

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:31', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'dae35b09-9192-428a-9065-d5ed08439ab9' User entered '14 Aug 2020 15:52'	System	14 Aug 2020 20:52:33
	System	14 Aug 2020 20:52:33

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 3'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:42:20', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1ce75ce3-d99e-4650-8e76-0614be0d8588' User entered 'Yes (Y)'	System	16 Aug 2020 00:42:58
	System	16 Aug 2020 00:42:58

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:42:41', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1ce75ce3-d99e-4650-8e76-0614be0d8588' User entered '98.1'	System	16 Aug 2020 00:42:58
	System	16 Aug 2020 00:42:58

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:42:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1ce75ce3-d99e-4650-8e76-0614be0d8588'	System	16 Aug 2020 00:42:58
User entered 'No (N)'	System	16 Aug 2020 00:42:58

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:42:53', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1ce75ce3-d99e-4650-8e76-0614be0d8588' User entered '15 Aug 2020 19:42'	System	16 Aug 2020 00:42:58
	System	16 Aug 2020 00:42:58

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 4'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:07', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'bc2e1dc1-8f35-4bbc-a0b3-97730484997b' User entered 'Yes (Y)'	System	16 Aug 2020 17:34:24
	System	16 Aug 2020 17:34:24

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:14', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'bc2e1dc1-8f35-4bbc-a0b3-97730484997b' User entered '98.9'	System	16 Aug 2020 17:34:24
	System	16 Aug 2020 17:34:24

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:17', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'bc2e1dc1-8f35-4bbc-a0b3-97730484997b'	System	16 Aug 2020 17:34:24
User entered 'No (N)'	System	16 Aug 2020 17:34:24

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:20', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'bc2e1dc1-8f35-4bbc-a0b3-97730484997b' User entered '16 Aug 2020 12:34'	System	16 Aug 2020 17:34:24
	System	16 Aug 2020 17:34:24

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 5'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:02', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e42ef3bc-2c31-43bf-bae4-3c6dea446ec0' User entered 'Yes (Y)'	System	17 Aug 2020 22:15:17
	System	17 Aug 2020 22:15:17

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:08', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e42ef3bc-2c31-43bf-bae4-3c6dea446ec0' User entered '98.9'	System	17 Aug 2020 22:15:17
	System	17 Aug 2020 22:15:17

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:11', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e42ef3bc-2c31-43bf-bae4-3c6dea446ec0'	System	17 Aug 2020 22:15:17
User entered 'No (N)'	System	17 Aug 2020 22:15:17

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:13', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'e42ef3bc-2c31-43bf-bae4-3c6dea446ec0' User entered '17 Aug 2020 17:15'	System	17 Aug 2020 22:15:17
	System	17 Aug 2020 22:15:17

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 6'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:12', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '369a945a-d4f6-4214-9d12-e022883ea11d' User entered 'Yes (Y)'	System	19 Aug 2020 03:31:28
	System	19 Aug 2020 03:31:28

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:18', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '369a945a-d4f6-4214-9d12-e022883ea11d' User entered '98.1'	System	19 Aug 2020 03:31:28
	System	19 Aug 2020 03:31:28

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:21', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '369a945a-d4f6-4214-9d12-e022883ea11d'	System	19 Aug 2020 03:31:28
User entered 'No (N)'	System	19 Aug 2020 03:31:28

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:25', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '369a945a-d4f6-4214-9d12-e022883ea11d' User entered '18 Aug 2020 22:31'	System	19 Aug 2020 03:31:28
	System	19 Aug 2020 03:31:28

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 7'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '71d37b6d-25a1-4f5a-9503-7ec3a1686953'	System	20 Aug 2020 03:04:16
User entered 'Yes (Y)'	System	20 Aug 2020 03:04:16

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '71d37b6d-25a1-4f5a-9503-7ec3a1686953' User entered '97.9'	System	20 Aug 2020 03:04:16
	System	20 Aug 2020 03:04:16

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:38', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '71d37b6d-25a1-4f5a-9503-7ec3a1686953'	System	20 Aug 2020 03:04:16
User entered 'No (N)'	System	20 Aug 2020 03:04:16

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:40', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '71d37b6d-25a1-4f5a-9503-7ec3a1686953'	System	20 Aug 2020 03:04:16
User entered '19 Aug 2020 22:00'	System	20 Aug 2020 03:04:16

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:53:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '50d4621a-7c4d-4053-9552-a1154515ebf8'	System	13 Aug 2020 17:54:17
User entered 'None (1)'	System	13 Aug 2020 17:54:17

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:53:43', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '50d4621a-7c4d-4053-9552-a1154515ebf8' User entered 'No (N)'	System	13 Aug 2020 17:54:17
	System	13 Aug 2020 17:54:17

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:53:54', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '50d4621a-7c4d-4053-9552-a1154515ebf8' User entered 'No (N)'	System	13 Aug 2020 17:54:17
	System	13 Aug 2020 17:54:17

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:11', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '50d4621a-7c4d-4053-9552-a1154515ebf8'	System	13 Aug 2020 17:54:17
User entered 'None (1)'	System	13 Aug 2020 17:54:17

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:15', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '50d4621a-7c4d-4053-9552-a1154515ebf8' User entered '13 Aug 2020 12:54'	System	13 Aug 2020 17:54:17
	System	13 Aug 2020 17:54:17

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 12:23'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 14:53'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:18', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd3b48b04-09fd-421e-b0a7-a0fe0022b689'	System	14 Aug 2020 02:16:35
User entered 'None (1)'	System	14 Aug 2020 02:16:35

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:24', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd3b48b04-09fd-421e-b0a7-a0fe0022b689'	System	14 Aug 2020 02:16:35
User entered 'No (N)'	System	14 Aug 2020 02:16:35

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:26', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd3b48b04-09fd-421e-b0a7-a0fe0022b689'	System	14 Aug 2020 02:16:35
User entered 'No (N)'	System	14 Aug 2020 02:16:35

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd3b48b04-09fd-421e-b0a7-a0fe0022b689'	System	14 Aug 2020 02:16:35
User entered 'None (1)'	System	14 Aug 2020 02:16:35

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:32', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd3b48b04-09fd-421e-b0a7-a0fe0022b689'	System	14 Aug 2020 02:16:35
User entered '13 Aug 2020 21:16'	System	14 Aug 2020 02:16:35

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 15:48'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 2'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:44', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '02fb5fca-00a1-428b-8f46-1e57cdd3dca2'	System	14 Aug 2020 20:53:19
User entered 'None (1)'	System	14 Aug 2020 20:53:19

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:52:57', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '02fb5fca-00a1-428b-8f46-1e57cdd3dca2'	System	14 Aug 2020 20:53:19
User entered 'No (N)'	System	14 Aug 2020 20:53:19

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:06', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '02fb5fca-00a1-428b-8f46-1e57cdd3dca2'	System	14 Aug 2020 20:53:19
User entered 'No (N)'	System	14 Aug 2020 20:53:19

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:12', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '02fb5fca-00a1-428b-8f46-1e57cdd3dca2'	System	14 Aug 2020 20:53:19
User entered 'None (1)'	System	14 Aug 2020 20:53:19

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:18', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '02fb5fca-00a1-428b-8f46-1e57cdd3dca2'	System	14 Aug 2020 20:53:19
User entered '14 Aug 2020 15:53'	System	14 Aug 2020 20:53:19

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 3'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:42:59', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37962d7e-af12-4a4f-b75f-467fcb477738'	System	16 Aug 2020 00:43:48
User entered 'None (1)'	System	16 Aug 2020 00:43:48

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:02', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37962d7e-af12-4a4f-b75f-467fcb477738'	System	16 Aug 2020 00:43:48
User entered 'No (N)'	System	16 Aug 2020 00:43:48

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:06', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37962d7e-af12-4a4f-b75f-467fcb477738'	System	16 Aug 2020 00:43:48
User entered 'No (N)'	System	16 Aug 2020 00:43:48

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:10', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37962d7e-af12-4a4f-b75f-467fcb477738'	System	16 Aug 2020 00:43:48
User entered 'None (1)'	System	16 Aug 2020 00:43:48

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37962d7e-af12-4a4f-b75f-467fcb477738'	System	16 Aug 2020 00:43:48
User entered '15 Aug 2020 19:43'	System	16 Aug 2020 00:43:48

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 4'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '821bac71-b529-4d7c-b59f-6686d77c4434'	System	16 Aug 2020 17:34:58
User entered 'None (1)'	System	16 Aug 2020 17:34:58

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:50', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '821bac71-b529-4d7c-b59f-6686d77c4434'	System	16 Aug 2020 17:34:58
User entered 'No (N)'	System	16 Aug 2020 17:34:58

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:51', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '821bac71-b529-4d7c-b59f-6686d77c4434' User entered 'No (N)'	System	16 Aug 2020 17:34:58
	System	16 Aug 2020 17:34:58

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:53', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '821bac71-b529-4d7c-b59f-6686d77c4434'	System	16 Aug 2020 17:34:58
User entered 'None (1)'	System	16 Aug 2020 17:34:58

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:56', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '821bac71-b529-4d7c-b59f-6686d77c4434' User entered '16 Aug 2020 12:34'	System	16 Aug 2020 17:34:58
	System	16 Aug 2020 17:34:58

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 5'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:22', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '7b07ff8c-2a62-4122-9949-63b476a53d6c'	System	17 Aug 2020 22:15:29
User entered 'None (1)'	System	17 Aug 2020 22:15:29

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:20', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '7b07ff8c-2a62-4122-9949-63b476a53d6c' User entered 'No (N)'	System	17 Aug 2020 22:15:29
	System	17 Aug 2020 22:15:29

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:24', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '7b07ff8c-2a62-4122-9949-63b476a53d6c' User entered 'No (N)'	System	17 Aug 2020 22:15:29
	System	17 Aug 2020 22:15:29

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:25', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '7b07ff8c-2a62-4122-9949-63b476a53d6c' User entered 'None (1)'	System	17 Aug 2020 22:15:29
	System	17 Aug 2020 22:15:29

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:28', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '7b07ff8c-2a62-4122-9949-63b476a53d6c' User entered '17 Aug 2020 17:15'	System	17 Aug 2020 22:15:29
	System	17 Aug 2020 22:15:29

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 6'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '75e4b28b-eb54-4220-8f75-247c9d8b9e4a'	System	19 Aug 2020 03:31:44
User entered 'None (1)'	System	19 Aug 2020 03:31:44

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:31', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '75e4b28b-eb54-4220-8f75-247c9d8b9e4a' User entered 'No (N)'	System	19 Aug 2020 03:31:44
	System	19 Aug 2020 03:31:44

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:34', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '75e4b28b-eb54-4220-8f75-247c9d8b9e4a' User entered 'No (N)'	System	19 Aug 2020 03:31:44
	System	19 Aug 2020 03:31:44

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:36', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '75e4b28b-eb54-4220-8f75-247c9d8b9e4a'	System	19 Aug 2020 03:31:44
User entered 'None (1)'	System	19 Aug 2020 03:31:44

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:39', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '75e4b28b-eb54-4220-8f75-247c9d8b9e4a' User entered '18 Aug 2020 22:31'	System	19 Aug 2020 03:31:44
	System	19 Aug 2020 03:31:44

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 7'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:10', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cc45765d-b119-4271-9d4e-1e96ee6fb865'	System	20 Aug 2020 03:04:25
User entered 'None (1)'	System	20 Aug 2020 03:04:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:12', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cc45765d-b119-4271-9d4e-1e96ee6fb865'	System	20 Aug 2020 03:04:25
User entered 'No (N)'	System	20 Aug 2020 03:04:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:15', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cc45765d-b119-4271-9d4e-1e96ee6fb865'	System	20 Aug 2020 03:04:25
User entered 'No (N)'	System	20 Aug 2020 03:04:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:20', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cc45765d-b119-4271-9d4e-1e96ee6fb865'	System	20 Aug 2020 03:04:25
User entered 'None (1)'	System	20 Aug 2020 03:04:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:26', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cc45765d-b119-4271-9d4e-1e96ee6fb865'	System	20 Aug 2020 03:04:25
User entered '19 Aug 2020 22:01'	System	20 Aug 2020 03:04:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:22', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:41', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:54:54', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered 'None (0)'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:55:03', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d'	System	13 Aug 2020 17:55:15
User entered 'No (N)'	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T12:55:14', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5a7145df-6d4f-45c4-9145-c27df6fa4a1d' User entered '13 Aug 2020 12:55'	System	13 Aug 2020 17:55:15
	System	13 Aug 2020 17:55:15

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 12:23'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 14:53'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:36', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:39', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:40', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:41', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:16:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:17:18', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'None (0)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:17:27', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered 'No (N)'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-13T21:17:33', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '98abb225-2df6-4b25-b28c-ad261cdece5f' User entered '13 Aug 2020 21:17'	System	14 Aug 2020 02:17:35
	System	14 Aug 2020 02:17:35

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '13 Aug 2020 15:48'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 2'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:22', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575'	System	14 Aug 2020 20:53:49
User entered 'None (0)'	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:27', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575' User entered 'None (0)'	System	14 Aug 2020 20:53:49
	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:29', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575' User entered 'None (0)'	System	14 Aug 2020 20:53:49
	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:33', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575' User entered 'None (0)'	System	14 Aug 2020 20:53:49
	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575' User entered 'None (0)'	System	14 Aug 2020 20:53:49
	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:37', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575' User entered 'None (0)'	System	14 Aug 2020 20:53:49
	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:44', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575'	System	14 Aug 2020 20:53:49
User entered 'No (N)'	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-14T15:53:47', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'da65d17c-ad83-4f98-848b-3ccda9fbb575'	System	14 Aug 2020 20:53:49
User entered '14 Aug 2020 15:53'	System	14 Aug 2020 20:53:49

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 3'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:51', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:43:53', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:03', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:05', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:07', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:13', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'None (0)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered 'No (N)'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-15T19:44:51', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1bb9c374-06c4-40ec-bd2a-643cd0fa7a46'	System	16 Aug 2020 00:44:54
User entered '15 Aug 2020 19:44'	System	16 Aug 2020 00:44:54

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 4'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:23', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered 'None (0)'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:25', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a' User entered 'None (0)'	System	16 Aug 2020 17:34:45
	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:26', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered 'None (0)'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:28', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a' User entered 'None (0)'	System	16 Aug 2020 17:34:45
	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:33', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered 'None (0)'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered 'None (0)'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:38', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered 'No (N)'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-16T12:34:41', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72b2f9f2-eef2-4071-a620-7f0bcfd2d45a'	System	16 Aug 2020 17:34:45
User entered '16 Aug 2020 12:34'	System	16 Aug 2020 17:34:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 5'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:31', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731'	System	17 Aug 2020 22:15:45
User entered 'None (0)'	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:32', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'None (0)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:34', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'None (0)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'None (0)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:37', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'None (0)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:38', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'None (0)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:40', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731' User entered 'No (N)'	System	17 Aug 2020 22:15:45
	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-17T17:15:42', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cde75b89-9284-4c10-9b16-ed141a29c731'	System	17 Aug 2020 22:15:45
User entered '17 Aug 2020 17:15'	System	17 Aug 2020 22:15:45

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 6'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:44', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:49', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:51', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:54', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:56', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'None (0)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:31:57', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered 'No (N)'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-18T22:32:04', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '16939746-48c9-45af-991a-b8940b788721' User entered '18 Aug 2020 22:32'	System	19 Aug 2020 03:32:06
	System	19 Aug 2020 03:32:06

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 7'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:44', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:47', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:50', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:51', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:54', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48' User entered 'None (0)'	System	20 Aug 2020 03:04:21
	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:00:58', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48'	System	20 Aug 2020 03:04:21
User entered 'No (N)'	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-08-19T22:01:05', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'df8a612f-507e-4c8a-ace0-586143252c48'	System	20 Aug 2020 03:04:21
User entered '19 Aug 2020 22:01'	System	20 Aug 2020 03:04:21

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:14:25

US3312063

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:13:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	20 Aug 2020 18:48:07

US3312063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '20 Aug 2020'	(b) (4) Kelly Moen (b) (4) (b) (4)	20 Aug 2020 18:48:07

US3312063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelly Moen (b) (4) (b) (4)	20 Aug 2020 18:48:07

US3312063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	20 Aug 2020 18:48:07

US3312063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	20 Aug 2020 18:48:28

US3312063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'I'	System	20 Aug 2020 18:48:28

US3312063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	06 Nov 2020 23:38:00
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:16:29
User entered 'No (N)'	Karol Moore (b) (4)	17 Sep 2020 13:16:29
	(b) (4)	

US3312063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:16:29

US3312063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4)	06 Nov 2020 23:38:00
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karol Moore (b) (4)	17 Sep 2020 13:16:29
	(b) (4)	

US3312063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'N/A occurred during convalescent period'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:16:29

US3312063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:16:39

US3312063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:05:48
User entered 'I'	System	17 Sep 2020 13:16:39

US3312063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 13:17:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '03 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:17:03

US3312063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:17:03

US3312063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:17:03
	(b) (4)	

US3312063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:17:08

US3312063

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:34:29
User entered 'I'	System	17 Sep 2020 13:17:08

US3312063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:21:24

US3312063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:21:24

US3312063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:21:24

US3312063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'VISIT2'	System	17 Sep 2020 13:21:24

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '15:56'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '10 Sep 2020 15:56'	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '98.4' F	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '59'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'bpm'	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '14'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'breaths/min'	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '115'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'mmHg'	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'mmHg'	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:22:44

US3312063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:56

US3312063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:22:56

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Karol Moore (b) (4)	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'loss of taste and smell persists despite negative covid test. per PI will affect ability for monitoring for covid symptoms'	Karol Moore (b) (4)	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4)	17 Sep 2020 13:20:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4)	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4)	17 Sep 2020 13:20:53
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:20:53

US3312063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:21

US3312063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:21

US3312063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '13:07'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:21

US3312063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '10 Sep 2020 13:07'	System	17 Sep 2020 13:23:21

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '12:45'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '10 Sep 2020 12:45'	System	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered empty.	System	17 Sep 2020 13:23:34

US3312063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	17 Sep 2020 13:23:40

US3312063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '1'	System	17 Sep 2020 13:23:40

US3312063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	21 Sep 2020 18:38:45

US3312063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '17 Sep 2020'	(b) (4) Monica Atwood (b) (4)	21 Sep 2020 18:38:45

US3312063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	21 Sep 2020 18:38:45

US3312063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Monica Atwood (b) (4)	21 Sep 2020 18:38:45

US3312063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	21 Sep 2020 18:38:58

US3312063

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'I'	System	21 Sep 2020 18:38:58

US3312063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:34:13

US3312063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '24 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:34:13

US3312063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:34:13

US3312063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4)	24 Sep 2020 21:34:13
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	24 Sep 2020 21:34:20

US3312063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'I'	System	24 Sep 2020 21:34:20

US3312063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 17:03:48

US3312063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '1 Oct 2020'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 17:03:48

US3312063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 17:03:48

US3312063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 17:03:48

US3312063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	05 Oct 2020 17:03:52

US3312063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'I'	System	05 Oct 2020 17:03:52

US3312063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'VISIT3'	System	12 Oct 2020 21:58:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '15:09'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '8 Oct 2020 15:09'	System	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '90'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'bpm'	System	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '14'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'breaths/min'	System	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '134'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'mmHg'	System	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '87'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'mmHg'	System	12 Oct 2020 21:58:49

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02

US3312063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:59

US3312063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:58:59

US3312063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:03:14

US3312063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:03:14

US3312063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered '15:30'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 22:03:14

US3312063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '8 Oct 2020 15:30'	System	12 Oct 2020 22:03:14

US3312063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:45:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 21:57:50

US3312063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered '1'	System	12 Oct 2020 21:57:50

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 64'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-14T08:47:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '10bd8061-8b77-468c-a272-9e86f30277ab' User entered 'No (N)'	System	14 Oct 2020 13:47:58
	System	14 Oct 2020 13:47:58

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-14T08:47:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '10bd8061-8b77-468c-a272-9e86f30277ab'	System	14 Oct 2020 13:47:58
User entered 'No (N)'	System	14 Oct 2020 13:47:58

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-14T08:47:55', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '10bd8061-8b77-468c-a272-9e86f30277ab' User entered '14 Oct 2020 08:47:55'	System	14 Oct 2020 13:47:58
	System	14 Oct 2020 13:47:58

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 71'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-21T12:52:30', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd0fd65ac-b639-4534-8be6-b2a292f962ab' User entered 'No (N)'	System	21 Oct 2020 17:52:51
	System	21 Oct 2020 17:52:51

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-21T12:52:33', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd0fd65ac-b639-4534-8be6-b2a292f962ab'	System	21 Oct 2020 17:52:51
User entered 'No (N)'	System	21 Oct 2020 17:52:51

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-21T12:52:40', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd0fd65ac-b639-4534-8be6-b2a292f962ab' User entered '21 Oct 2020 12:52:40'	System	21 Oct 2020 17:52:51
	System	21 Oct 2020 17:52:51

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 78'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-27T13:00:43', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2c035364-c66e-4e7e-b8a2-d4f7079228ba' User entered 'Yes (Y)'	System	27 Oct 2020 18:01:11
	System	27 Oct 2020 18:01:11

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-27T13:00:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2c035364-c66e-4e7e-b8a2-d4f7079228ba' User entered 'No (N)'	System	27 Oct 2020 18:01:11
	System	27 Oct 2020 18:01:11

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-27T13:00:57', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2c035364-c66e-4e7e-b8a2-d4f7079228ba' User entered 'No (N)'	System	27 Oct 2020 18:01:11
	System	27 Oct 2020 18:01:11

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-27T13:01:01', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2c035364-c66e-4e7e-b8a2-d4f7079228ba' User entered 'No (N)'	System	27 Oct 2020 18:01:11
	System	27 Oct 2020 18:01:11

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-10-27T13:01:07', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '2c035364-c66e-4e7e-b8a2-d4f7079228ba' User entered '27 Oct 2020 13:01:07'	System	27 Oct 2020 18:01:11
	System	27 Oct 2020 18:01:11

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 92'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-11T09:07:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'c43a0c3c-9da1-4403-b367-358cb5b3fd95'	System	11 Nov 2020 15:07:59
User entered 'No (N)'	System	11 Nov 2020 15:07:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-11T09:07:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'c43a0c3c-9da1-4403-b367-358cb5b3fd95'	System	11 Nov 2020 15:07:59
User entered 'No (N)'	System	11 Nov 2020 15:07:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-11T09:07:55', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'c43a0c3c-9da1-4403-b367-358cb5b3fd95' User entered '11 Nov 2020 09:07:55'	System	11 Nov 2020 15:07:59
	System	11 Nov 2020 15:07:59

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:20:56
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39
Data entry locked.	System	13 Aug 2020 17:14:25
User entered 'Day 99'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:14:25

US3312063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 06:10:39
Data entry locked.	System	13 Aug 2020 17:14:25
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:14:25

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-22T13:09:27', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '580972d5-245d-4ad6-837c-8fc30247c64d' User entered 'No (N)'	System	22 Nov 2020 19:09:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-22T13:09:30', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '580972d5-245d-4ad6-837c-8fc30247c64d' User entered 'No (N)'	System	22 Nov 2020 19:09:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-22T13:09:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '580972d5-245d-4ad6-837c-8fc30247c64d' User entered '22 Nov 2020 13:09:35'	System	22 Nov 2020 19:09:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-29T13:53:34', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'eba803ab-637b-4d97-bb14-66f11a073f49' User entered 'No (N)'	System	29 Nov 2020 19:53:45
	System	29 Nov 2020 19:53:45

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-29T13:53:37', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'eba803ab-637b-4d97-bb14-66f11a073f49' User entered 'No (N)'	System	29 Nov 2020 19:53:45

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-11-29T13:53:40', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'eba803ab-637b-4d97-bb14-66f11a073f49' User entered '29 Nov 2020 13:53:40'	System	29 Nov 2020 19:53:45
	System	29 Nov 2020 19:53:45

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-05T18:18:56', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '3207ad13-4455-4c1f-b844-6d5ba0ca0d68' User entered 'No (N)'	System	06 Dec 2020 00:19:26
	System	06 Dec 2020 00:19:26

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-05T18:19:01', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '3207ad13-4455-4c1f-b844-6d5ba0ca0d68' User entered 'No (N)'	System	06 Dec 2020 00:19:26
	System	06 Dec 2020 00:19:26

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-05T18:19:23', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '3207ad13-4455-4c1f-b844-6d5ba0ca0d68' User entered '05 Dec 2020 18:19:23'	System	06 Dec 2020 00:19:26
	System	06 Dec 2020 00:19:26

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-15T07:25:12', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '6ed5a476-7c0e-420e-849a-7623d19fea32'	System	15 Dec 2020 13:25:28
User entered 'No (N)'	System	15 Dec 2020 13:25:28

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-15T07:25:14', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '6ed5a476-7c0e-420e-849a-7623d19fea32'	System	15 Dec 2020 13:25:28
User entered 'No (N)'	System	15 Dec 2020 13:25:28

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-15T07:25:26', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '6ed5a476-7c0e-420e-849a-7623d19fea32' User entered '15 Dec 2020 07:25:26'	System	15 Dec 2020 13:25:28
	System	15 Dec 2020 13:25:28

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-21T17:07:13', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '4bc7c77a-45e5-4602-83a6-e8ab45fe37ca' User entered 'No (N)'	System	21 Dec 2020 23:07:25
	System	21 Dec 2020 23:07:25

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-21T17:07:15', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '4bc7c77a-45e5-4602-83a6-e8ab45fe37ca' User entered 'No (N)'	System	21 Dec 2020 23:07:25
	System	21 Dec 2020 23:07:25

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-21T17:07:23', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '4bc7c77a-45e5-4602-83a6-e8ab45fe37ca' User entered '21 Dec 2020 17:07:23'	System	21 Dec 2020 23:07:25
	System	21 Dec 2020 23:07:25

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-29T20:19:55', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'fef3c907-c8c5-4b49-a067-60fdbbd95d38'	System	30 Dec 2020 02:20:07
User entered 'No (N)'	System	30 Dec 2020 02:20:07

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-29T20:19:57', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'fef3c907-c8c5-4b49-a067-60fdbbd95d38'	System	30 Dec 2020 02:20:07
User entered 'No (N)'	System	30 Dec 2020 02:20:07

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2020-12-29T20:20:02', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'fef3c907-c8c5-4b49-a067-60fdbbd95d38' User entered '29 Dec 2020 20:20:02'	System	30 Dec 2020 02:20:07
	System	30 Dec 2020 02:20:07

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-06T07:51:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cddf94db-56ef-4517-9605-8207fb9e8d3b'	System	06 Jan 2021 14:00:46
User entered 'No (N)'	System	06 Jan 2021 14:00:46

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-06T07:51:50', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cddf94db-56ef-4517-9605-8207fb9e8d3b'	System	06 Jan 2021 14:00:46
User entered 'No (N)'	System	06 Jan 2021 14:00:46

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-06T07:51:53', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cddf94db-56ef-4517-9605-8207fb9e8d3b' User entered '06 Jan 2021 07:51:53'	System	06 Jan 2021 14:00:46
	System	06 Jan 2021 14:00:46

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-09T20:40:26', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '15496502-f758-44ae-8981-0f4e3c4699fe' User entered 'No (N)'	System	10 Jan 2021 02:51:35

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-09T20:51:24', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '15496502-f758-44ae-8981-0f4e3c4699fe' User entered 'No (N)'	System	10 Jan 2021 02:51:35

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-09T20:51:32', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '15496502-f758-44ae-8981-0f4e3c4699fe' User entered '09 Jan 2021 20:51:32'	System	10 Jan 2021 02:51:35
	System	10 Jan 2021 02:51:35

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-17T13:28:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'a9ec31a7-d740-4d66-bbb6-099da13e5cf0' User entered 'No (N)'	System	17 Jan 2021 19:29:06
	System	17 Jan 2021 19:29:06

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-17T13:28:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'a9ec31a7-d740-4d66-bbb6-099da13e5cf0' User entered 'No (N)'	System	17 Jan 2021 19:29:06
	System	17 Jan 2021 19:29:06

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-17T13:29:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'a9ec31a7-d740-4d66-bbb6-099da13e5cf0' User entered '17 Jan 2021 13:29:00'	System	17 Jan 2021 19:29:06
	System	17 Jan 2021 19:29:06

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-25T12:52:42', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cafdda6b-2947-43e0-9cb5-73d2a021c423'	System	25 Jan 2021 18:52:52
User entered 'No (N)'	System	25 Jan 2021 18:52:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-25T12:52:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cafdda6b-2947-43e0-9cb5-73d2a021c423'	System	25 Jan 2021 18:52:52
User entered 'No (N)'	System	25 Jan 2021 18:52:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-01-25T12:52:50', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'cafdda6b-2947-43e0-9cb5-73d2a021c423' User entered '25 Jan 2021 12:52:50'	System	25 Jan 2021 18:52:52
	System	25 Jan 2021 18:52:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-02T11:42:46', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5f806378-687b-4e46-a0a3-d4c6cd7c97e3' User entered 'No (N)'	System	02 Feb 2021 17:42:57
	System	02 Feb 2021 17:42:57

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-02T11:42:49', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5f806378-687b-4e46-a0a3-d4c6cd7c97e3' User entered 'No (N)'	System	02 Feb 2021 17:42:57

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-02T11:42:54', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '5f806378-687b-4e46-a0a3-d4c6cd7c97e3' User entered '02 Feb 2021 11:42:54'	System	02 Feb 2021 17:42:57
	System	02 Feb 2021 17:42:57

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-08T12:00:31', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'ccad06df-3f4d-4130-9b8b-7edcd2045101'	System	08 Feb 2021 18:01:18
User entered 'No (N)'	System	08 Feb 2021 18:01:18

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-08T12:00:35', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'ccad06df-3f4d-4130-9b8b-7edcd2045101'	System	08 Feb 2021 18:01:18
User entered 'No (N)'	System	08 Feb 2021 18:01:18

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-08T12:00:39', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'ccad06df-3f4d-4130-9b8b-7edcd2045101' User entered '08 Feb 2021 12:00:39'	System	08 Feb 2021 18:01:18
	System	08 Feb 2021 18:01:18

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-16T08:10:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '654d53af-e608-4caa-8cb2-1f2588183178' User entered 'No (N)'	System	16 Feb 2021 14:10:56
	System	16 Feb 2021 14:10:56

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-16T08:10:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '654d53af-e608-4caa-8cb2-1f2588183178' User entered 'No (N)'	System	16 Feb 2021 14:10:56
	System	16 Feb 2021 14:10:56

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-16T08:10:53', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '654d53af-e608-4caa-8cb2-1f2588183178' User entered '16 Feb 2021 08:10:53'	System	16 Feb 2021 14:10:56
	System	16 Feb 2021 14:10:56

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-20T08:23:43', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '88134470-9630-4c7b-a391-49cb0c5bb7fa' User entered 'No (N)'	System	20 Feb 2021 14:23:52
	System	20 Feb 2021 14:23:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-20T08:23:45', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '88134470-9630-4c7b-a391-49cb0c5bb7fa' User entered 'No (N)'	System	20 Feb 2021 14:23:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-02-20T08:23:48', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '88134470-9630-4c7b-a391-49cb0c5bb7fa' User entered '20 Feb 2021 08:23:48'	System	20 Feb 2021 14:23:52
	System	20 Feb 2021 14:23:52

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-16T19:32:19-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37cd08a5-8124-4cfa-bb91-52560ef29b3f'	System	17 Mar 2021 00:32:29
User entered 'No (N)'	System	17 Mar 2021 00:32:29

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-16T19:32:23-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37cd08a5-8124-4cfa-bb91-52560ef29b3f' User entered 'No (N)'	System	17 Mar 2021 00:32:29
	System	17 Mar 2021 00:32:29

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-16T19:32:25-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '37cd08a5-8124-4cfa-bb91-52560ef29b3f'	System	17 Mar 2021 00:32:29
User entered '16 Mar 2021 19:32:25'	System	17 Mar 2021 00:32:29

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-21T12:54:22-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '09f1252f-f480-49ab-b7f0-60a7d600c919'	System	21 Mar 2021 17:54:30
User entered 'No (N)'	System	21 Mar 2021 17:54:30

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-21T12:54:24-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '09f1252f-f480-49ab-b7f0-60a7d600c919'	System	21 Mar 2021 17:54:30
User entered 'No (N)'	System	21 Mar 2021 17:54:30

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-21T12:54:27-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '09f1252f-f480-49ab-b7f0-60a7d600c919'	System	21 Mar 2021 17:54:30
User entered '21 Mar 2021 12:54:27'	System	21 Mar 2021 17:54:30

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-04T18:04:44-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1323eda0-dc2d-4fb2-a70b-ac44184584c4' User entered 'No (N)'	System	04 Apr 2021 23:06:23
	System	04 Apr 2021 23:06:23

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-04T18:04:47-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1323eda0-dc2d-4fb2-a70b-ac44184584c4' User entered 'No (N)'	System	04 Apr 2021 23:06:23
	System	04 Apr 2021 23:06:23

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-04T18:04:50-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '1323eda0-dc2d-4fb2-a70b-ac44184584c4'	System	04 Apr 2021 23:06:23
User entered '04 Apr 2021 18:04:50'	System	04 Apr 2021 23:06:23

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-13T09:00:33-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '63b3fcd4-b424-4eba-ae38-7ae64250bb85'	System	13 Apr 2021 14:00:49
User entered 'No (N)'	System	13 Apr 2021 14:00:49

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-13T09:00:36-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '63b3fcd4-b424-4eba-ae38-7ae64250bb85'	System	13 Apr 2021 14:00:49
User entered 'No (N)'	System	13 Apr 2021 14:00:49

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-13T09:00:42-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '63b3fcd4-b424-4eba-ae38-7ae64250bb85'	System	13 Apr 2021 14:00:49
User entered '13 Apr 2021 09:00:42'	System	13 Apr 2021 14:00:49

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-20T08:41:45-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '306b5a81-d340-428a-b792-b9a2bad142cb'	System	20 Apr 2021 13:41:53
User entered 'No (N)'	System	20 Apr 2021 13:41:53

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-20T08:41:47-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '306b5a81-d340-428a-b792-b9a2bad142cb'	System	20 Apr 2021 13:41:53
User entered 'No (N)'	System	20 Apr 2021 13:41:53

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-20T08:41:49-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '306b5a81-d340-428a-b792-b9a2bad142cb' User entered '20 Apr 2021 08:41:49'	System	20 Apr 2021 13:41:53
	System	20 Apr 2021 13:41:53

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-25T18:49:02-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '67a5bbaf-32e0-4d28-aec9-2cc0884e235c'	System	25 Apr 2021 23:49:13
User entered 'No (N)'	System	25 Apr 2021 23:49:13

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-25T18:49:05-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '67a5bbaf-32e0-4d28-aec9-2cc0884e235c' User entered 'No (N)'	System	25 Apr 2021 23:49:13

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-04-25T18:49:11-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '67a5bbaf-32e0-4d28-aec9-2cc0884e235c'	System	25 Apr 2021 23:49:13
User entered '25 Apr 2021 18:49:11'	System	25 Apr 2021 23:49:13

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-05-03T12:00:25-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72ae1e80-3232-4423-acd6-59a2623031d3'	System	03 May 2021 17:01:02
User entered 'No (N)'	System	03 May 2021 17:01:02

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-05-03T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72ae1e80-3232-4423-acd6-59a2623031d3'	System	03 May 2021 17:01:02
User entered 'No (N)'	System	03 May 2021 17:01:02

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-05-03T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: '72ae1e80-3232-4423-acd6-59a2623031d3'	System	03 May 2021 17:01:02
User entered '03 May 2021 12:00:30'	System	03 May 2021 17:01:02

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:10:39

US3312063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:13:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:10:39
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:10:39

US3312063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:13:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-16T19:32:32-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd22f3d81-e326-4e2e-84b0-3f9efc201c9e'	System	17 Mar 2021 00:32:42
User entered 'No (N)'	System	17 Mar 2021 00:32:42

US3312063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:13:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:40:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0AB3A67-C7EA-421C-969B-490B1FCE55AC)', Time: '2021-03-16T19:32:38-05:00', User OID: 'PatientReportedOutcome (US3312063)', ODM File OID: 'd22f3d81-e326-4e2e-84b0-3f9efc201c9e'	System	17 Mar 2021 00:32:42
User entered '16 Mar 2021 19:32:38'	System	17 Mar 2021 00:32:42

US3312063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:56

US3312063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:56

US3312063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:56

US3312063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:25:56

US3312063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:26:00

US3312063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:24:02
User entered 'I'	System	06 Nov 2020 14:26:00

US3312063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:39:51

US3312063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:39:51

US3312063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:39:51

US3312063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:39:51

US3312063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:39:56

US3312063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered '1'	System	10 Dec 2020 16:39:56

US3312063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:02:22

US3312063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:02:22

US3312063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:02:22

US3312063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:02:22

US3312063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:02:26

US3312063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered 'I'	System	06 Jan 2021 16:02:26

US3312063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4)	08 Feb 2021 21:19:16
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '04 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:19:16

US3312063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:19:16

US3312063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4)	08 Feb 2021 21:19:16
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:19:19

US3312063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered '1'	System	08 Feb 2021 21:19:19

US3312063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:40

US3312063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:40

US3312063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:40

US3312063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered 'VISIT4'	System	19 Mar 2021 13:57:40

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered empty.	System	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered empty.	System	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered empty.	System	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered empty.	System	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered empty.	System	29 Mar 2021 18:04:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06

US3312063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:46

US3312063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:46

US3312063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:57

US3312063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:57

US3312063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '08:23'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:57:57

US3312063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered '19 Mar 2021 08:23'	System	19 Mar 2021 13:57:57

US3312063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:58:00

US3312063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:06
User entered '1'	System	19 Mar 2021 13:58:00

US3312063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:48

US3312063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:05
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:48

US3312063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:48

US3312063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:05
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:48

US3312063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User signature succeeded.	Carlos Fierro (b) (4)	06 Apr 2021 19:25:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:45:52

US3312063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:32
User entered 'I'	System	06 Apr 2021 18:45:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:42

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:47:46
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:21:23

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:42

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '08:00'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:21:23

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:42

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:13
User entered '24 Aug 2020 08:00'	System	25 Aug 2020 15:47:46
User entered '25 Aug 2020 08:00'	System	25 Aug 2020 15:21:23

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:42

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:47:46
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	25 Aug 2020 15:21:23

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:13:42

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:21:23

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	23 Oct 2020 20:49:33
Data Entry Error	(b) (4)	
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:57
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:57
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:28:34
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:01

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	23 Oct 2020 20:49:33
Data Entry Error	(b) (4)	
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:32:32

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	23 Oct 2020 20:49:33
Data Entry Error	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:17:57

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	23 Oct 2020 20:49:33
Data Entry Error	Karol Moore (b) (4)	
User entered 'Day 4 (Day 4)'	(b) (4)	02 Sep 2020 01:19:52
	(b) (4), (b) (6)	

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '96'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 01:19:52

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	18 Dec 2020 16:33:09
User entered empty.	System	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 20:52:01
User entered 'Mild (Mild)'	Karol Moore (b) (4)	23 Oct 2020 20:51:44
	(b) (4)	

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:51:44

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '22 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	18 Dec 2020 16:33:09
User entered empty.	System	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:52:46

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '23 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	18 Dec 2020 16:33:09
User entered empty.	System	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:53:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '24 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User entered '%'	System	18 Dec 2020 16:33:09
User entered empty.	System	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:09
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:13:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Oct 2020 20:54:19

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 01:15:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 01:15:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 01:15:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 15:25:39
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:25:39

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:13:42

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:06
User entered '0'	System	02 Sep 2020 01:15:42

US3312063

Folder: Covid-19 Assessment 24 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:13:42

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:14:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:11:58

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Sep 2020 20:40:35

US3312063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'SICKD1'	System	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '08:17'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered '25 Aug 2020 08:17'	System	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '73.0' in	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15
DataPoint set to visible.	System	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '218' lb	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15
DataPoint set to visible.	System	25 Aug 2020 15:50:11

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '99'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'bpm'	System	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'breaths/min'	System	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '140'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'mmHg'	System	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '94'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User entered 'mmHg'	System	25 Aug 2020 15:51:15

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39

US3312063

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39

US3312063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:25

US3312063

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:25

US3312063

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:13:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:33

US3312063

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:51:33

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Nov 2020 21:13:56
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:13:56
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:13:56
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	16 Nov 2020 21:13:56

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:14:14

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:14:14

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:14:14

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:14:14

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:14
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:14:14

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Nov 2020 21:14:19
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:19
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:13:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	16 Nov 2020 21:14:22
	(b) (4)	

US3312063

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:13:42

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	16 Nov 2020 21:14:22
	(b) (4)	

US3312063

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:45:17

US3312063

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:45:17

US3312063

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Feb 2021 13:45:17

US3312063

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

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 13:45:17

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:29:57

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:29:57

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered empty.	System	03 Feb 2021 13:46:04

US3312063

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

Form: Unblinding

Generated On: 11 Aug 2021 22:13:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'I'	System	03 Feb 2021 13:46:04

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered empty.	System	03 Feb 2021 13:53:26
DataPoint set to visible.	System	03 Feb 2021 13:46:04

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered empty.	System	03 Feb 2021 13:53:26
DataPoint set to visible.	System	03 Feb 2021 13:46:04

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '08:46'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered '22 Jan 2021 08:46'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '98.2' F	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '91'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'bpm'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '14'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'breaths/min'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '137'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'mmHg'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '85'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'mmHg'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:13:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered empty.	System	03 Feb 2021 13:53:26
DataPoint set to visible.	System	03 Feb 2021 13:46:04

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '10:21'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered '22 Jan 2021 10:21'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '97.9' F	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '88'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'bpm'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'breaths/min'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '105'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'mmHg'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '79'	(b) (4), (b) (6)	03 Feb 2021 13:53:26

US3312063

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'mmHg'	System	03 Feb 2021 13:53:26

US3312063

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:53:42

US3312063

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:53:42

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'mRNA-1273'	System	03 Feb 2021 14:00:38
DataPoint set to visible.	System	03 Feb 2021 13:46:04

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '09:51'	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered '22 Jan 2021 09:51'	System	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'ONCE'	System	03 Feb 2021 14:00:38

US3312063

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

Form: Exposure

Generated On: 11 Aug 2021 22:13:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 14:00:38

US3312063

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:46:13

US3312063

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:46:13

US3312063

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '08:32'	(b) (4), (b) (6)	03 Feb 2021 13:46:13

US3312063

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered '22 Jan 2021 08:32'	System	03 Feb 2021 13:46:13

US3312063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:46:21

US3312063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	03 Feb 2021 13:46:21

US3312063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '08:31'	(b) (4), (b) (6)	03 Feb 2021 13:46:21

US3312063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:13:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered '22 Jan 2021 08:31'	System	03 Feb 2021 13:46:21

US3312063

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

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:46:25

US3312063

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

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'I'	System	03 Feb 2021 13:46:25

US3312063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:41

US3312063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:41

US3312063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:41

US3312063

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:13:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:41

US3312063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:44

US3312063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered 'I'	System	03 Feb 2021 14:05:44

US3312063

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:13:42

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:45
User entered '1'	System	03 Feb 2021 14:05:44
DataPoint set to visible.	System	03 Feb 2021 14:05:44

US3312063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:35:40

US3312063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:35:40

US3312063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Home (Home)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:35:40

US3312063

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:13:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered 'OLD29'	System	22 Feb 2021 14:35:40

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '08:17'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered '19 Feb 2021 08:17'	System	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered 'bpm'	System	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered 'breaths/min'	System	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '149'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered 'mmHg'	System	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '83'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered 'mmHg'	System	22 Feb 2021 14:36:26

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33

US3312063

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:13:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33

US3312063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:37:01

US3312063

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:13:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:37:01

US3312063

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:38:53

US3312063

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:38:53

US3312063

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '08:36'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:38:53

US3312063

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:38:33
User entered '19 Feb 2021 08:36'	System	22 Feb 2021 14:38:53

US3312063

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:13:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:10:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 19:58:00

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:42:46
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:15
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:32:30
User closed query 'Per DM CLR: Please review AE #s 1 to 12 and verify if these symptoms are all related as the dates of these AEs are all overlapping. If these are related events, determine if these may be combined and recorded with one diagnosis. Please review and update applicable details as appropriate. Otherwise, provide comment. (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:46:14
Query 'Per DM CLR: Please review AE #s 1 to 12 and verify if these symptoms are all related as the dates of these AEs are all overlapping. If these are related events, determine if these may be combined and recorded with one diagnosis. Please review and update applicable details as appropriate. Otherwise, provide comment. answered with 'AEs #1-12 are correct as entered.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:55:56

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review AE #s 1 to 12 and verify if these symptoms are all related as the dates of these AEs are all overlapping. If these are related events, determine if these may be combined and recorded with one diagnosis. Please review and update applicable details as appropriate. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:40:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 20:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	23 Sep 2020 20:02:50
Data point term sent to Coder	System	23 Sep 2020 20:01:47
User entered 'fatigue'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '21 Aug 2020'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 20:01:10

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '27 Aug 2020'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 20:01:10

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'None (NONE)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'I'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	23 Sep 2020 20:01:10
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 20:01:10

US3312063

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 20:01:10

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:43:08
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:26
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:32:48
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:50:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:59:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:59:31

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'Confirmed muscle aches are generalized. No specific location specified.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:59:04
Data point term sent to Coder	System	23 Oct 2020 14:58:38
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 14:58:38
User entered 'Generalized MUSCLE ACHES' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 14:58:38
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Muscle Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:48:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:03:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:03:36
Data point term sent to Coder	System	23 Sep 2020 20:02:49
User entered 'muscle aches'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:02:19
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	23 Sep 2020 20:02:44
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Sep 2020 20:02:44
User entered '21 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 20:02:44
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	23 Sep 2020 20:02:19
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Sep 2020 20:02:19
User entered '21 Apr 2020'	Karol Moore (b) (4)	23 Sep 2020 20:02:19
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User entered empty.	System	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	23 Sep 2020 20:02:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Sep 2020 20:02:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Sep 2020 20:02:19
User entered '15 Sep 2020'	Karol Moore (b) (4)	23 Sep 2020 20:02:19
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User entered empty.	System	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	23 Sep 2020 20:02:19
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:02:19
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 20:02:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Karol Moore (b) (4)	23 Sep 2020 20:02:19
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User entered '0'	System	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12
User entered '1'	System	23 Sep 2020 20:02:19

US3312063

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:12

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 11:51:05
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Confirmed that the subject was arranged for an illness visit within 72 hours to collect an NP swab sample for testing for SARS-CoV-2 infection.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:54:48
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:46:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:04:39
Data point term sent to Coder	System	23 Sep 2020 20:03:51
User entered 'body aches'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User entered empty.	System	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User entered empty.	System	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:03:29
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User entered '0'	System	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17
User entered 'I'	System	23 Sep 2020 20:03:29

US3312063

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:17

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:43:30
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:35
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	29 Oct 2020 19:33:38
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Ageusia, LLT: Loss of taste - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:21:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:21:46
Data point term sent to Coder	System	23 Sep 2020 20:04:54
User entered 'new loss of taste'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:04:12
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User entered empty.	System	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '15 Sep 2020'	(b) (4)	23 Sep 2020 20:04:12
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User entered empty.	System	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:04:12
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:19:27
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'UPDATED.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 16:22:56
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Mar 2021 16:21:22
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 16:21:22
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User entered '0'	System	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19
User entered 'I'	System	23 Sep 2020 20:04:12

US3312063

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:19

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:47:51
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:40
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:33:21
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Loss of smell - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:21:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:21:46
Data point term sent to Coder	System	23 Sep 2020 20:05:59
User entered 'new loss of smell'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	23 Sep 2020 20:05:19
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Sep 2020 20:05:19
User entered '21 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 20:05:19
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	23 Sep 2020 20:05:05
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	23 Sep 2020 20:05:05
User entered '21 Apr 2020'	Karol Moore (b) (4)	23 Sep 2020 20:05:05
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User entered empty.	System	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '15 Sep 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User entered empty.	System	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:05:05
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:19:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'UPDATED.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 16:23:48
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Mar 2021 16:23:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 16:23:33
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User entered '0'	System	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24
User entered 'I'	System	23 Sep 2020 20:05:05

US3312063

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:43:24

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 20:07:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 20:07:48
Data point term sent to Coder	System	23 Sep 2020 20:07:00
User entered 'runny nose'	Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '25 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User entered empty.	System	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User entered empty.	System	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:06:12
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User entered '0'	System	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46
User entered 'I'	System	23 Sep 2020 20:06:12

US3312063

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:46

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:48:27
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:46
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:33:06
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:45
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:07:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:07:47
Data point term sent to Coder	System	23 Sep 2020 20:07:02
User entered 'nausea'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User entered empty.	System	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User entered empty.	System	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:07:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4)	23 Sep 2020 20:07:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User entered '0'	System	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53
User entered '1'	System	23 Sep 2020 20:07:01

US3312063

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:44:53

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:48:44
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:51
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:33:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:08:39
Data point term sent to Coder	System	23 Sep 2020 20:08:03
User entered 'vomiting'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User entered empty.	System	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '26 Aug 2020'	(b) (4)	23 Sep 2020 20:07:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User entered empty.	System	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	23 Sep 2020 20:07:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:07:41
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User entered '0'	System	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03
User entered 'I'	System	23 Sep 2020 20:07:41

US3312063

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:03

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query '1) Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). 2) Please confirm any concomitant medication was given' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:42:27
Query '1) Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). 2) Please confirm any concomitant medication was given' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:21:55
User opened query '1) Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). 2) Please confirm any concomitant medication was given' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:32:05
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:09:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:09:42
Data point term sent to Coder	System	23 Sep 2020 20:09:04
User entered 'diarrhea'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

PRODUCTION RELEASE (v12.003
EAB) (1725)

2007 of 2196

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User entered empty.	System	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User entered empty.	System	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:08:40
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4)	23 Sep 2020 20:08:40
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User entered '0'	System	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10
User entered 'I'	System	23 Sep 2020 20:08:40

US3312063

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:10

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:40:31
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:22:00
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:23:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:11:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:11:38
Data point term sent to Coder	System	23 Sep 2020 20:10:09
User entered 'chills'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '25 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User entered empty.	System	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User entered empty.	System	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:09:28
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User entered '0'	System	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12
User entered 'I'	System	23 Sep 2020 20:09:28

US3312063

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:12

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:41:51
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:22:04
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:31:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:11:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 20:11:38
Data point term sent to Coder	System	23 Sep 2020 20:11:11
User entered 'cough'	Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:10:14
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User entered empty.	System	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '26 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User entered empty.	System	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 20:11:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 20:11:01
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Sep 2020 20:11:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Sep 2020 20:10:14
User entered empty.	System	23 Sep 2020 20:10:14
	Karol Moore (b) (4)	23 Sep 2020 20:10:14
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:10:14
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User entered '0'	System	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19
User entered 'I'	System	23 Sep 2020 20:10:14

US3312063

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:19

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User closed query 'Per MM, If it is a nasal congestion, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:40:56
Query 'Per MM, If it is a nasal congestion, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'SEE ILLNESS VISIT 1 ENTERED 25AUG2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	16 Nov 2020 21:22:10
User opened query 'Per MM, If it is a nasal congestion, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:31:03
User closed query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:51:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:06:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:06:39
Data point term sent to Coder	System	23 Oct 2020 15:05:53

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'Updated term with specificity of nasal congestion.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:05:29
User closed query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	System	23 Oct 2020 15:05:25
Query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' answered with 'Updated term with specificity of nasal congestion.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 15:05:25
User entered 'Nasal CONGESTION' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 15:04:57
User opened query 'Per DM CLR: Please review AE and please update to specify the location/type of Congestion. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:40:20
User opened query 'DM-Coding: The verbatim CONGESTION cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	24 Sep 2020 18:42:34
Data point term sent to Coder	System	23 Sep 2020 20:11:12
User entered 'congestion'	Karol Moore (b) (4)	23 Sep 2020 20:10:52
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User entered empty.	System	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '27 Aug 2020'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User entered empty.	System	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	23 Sep 2020 20:10:52
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	23 Sep 2020 20:10:52
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4)	23 Sep 2020 20:10:52
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'None (NONE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User entered '0'	System	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24
User entered 'I'	System	23 Sep 2020 20:10:52

US3312063

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:24

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Humerus fracture, LLT: Humerus fracture - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 21:22:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Feb 2021 21:22:38
Data point term sent to Coder	System	08 Feb 2021 21:22:03
User entered 'LEFT HUMERUS FRACTURE'	Karol Moore (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	08 Feb 2021 21:21:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '30 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User entered empty.	System	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '30 Nov 2020'	(b) (4) Karol Moore (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User entered empty.	System	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'No (N)'	(b) (4)	08 Feb 2021 21:21:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4)	08 Feb 2021 21:21:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	08 Feb 2021 21:21:44
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:44:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User entered '0'	System	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27
User entered 'I'	System	08 Feb 2021 21:21:44

US3312063

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 11 Aug 2021 22:13:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:45:27

US3312063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:13:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	08 Feb 2021 21:21:57
	(b) (4)	

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:13:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'Yes (Y)'	(b) (4)	08 Feb 2021 21:22:07
	Karol Moore (b) (4)	
	(b) (4)	

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:13:42

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered '30 Nov 2020'	Karol Moore (b) (4)	08 Feb 2021 21:22:34
	(b) (4)	

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:13:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'SURGICAL REPAIR OF LEFT HUMERUS FRACTURE'	Karol Moore (b) (4)	08 Feb 2021 21:22:34
	(b) (4)	

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:13:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Karol Moore (b) (4)	08 Feb 2021 21:22:34
	(b) (4)	

US3312063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:13:42

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	08 Feb 2021 21:22:34
	(b) (4)	

US3312063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:13:42

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Dec 2020 21:15:09

US3312063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:13:42

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:24:08
User entered 'Physician decision (specify) (PHYSICIAN DECISION)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 16:20:26
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	15 Dec 2020 21:15:09

US3312063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:44:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:33:17
User closed query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:52:16
Query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' answered with 'updated' (Site from DM).	Kelly Moen (b) (4) (b) (4)	18 Mar 2021 17:58:27
User entered 'AE # 4 and # 5' reason for change: Data Entry Error	Kelly Moen (b) (4) (b) (4)	18 Mar 2021 17:58:19
User opened query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:15:08
User closed query 'Per CDM: Please be aware that "Inclusion Criteria 3" cannot be entered. Please provide here actual reason why subject discontinued dosing. "Visit 2" Exposure form states that was physician decision because of taste or smell lost and AE is entered. However, AE is entered but no "Investigation product withdrawn". Please review all the necessary forms and update accordingly. Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:19:02
Query 'Per CDM: Please be aware that "Inclusion Criteria 3" cannot be entered. Please provide here actual reason why subject discontinued dosing. "Visit 2" Exposure form states that was physician decision because of taste or smell lost and AE is entered. However, AE is entered but no "Investigation product withdrawn". Please review all the necessary forms and update accordingly. Thank you!' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 16:20:36

US3312063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:13:42

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

Audit	User	Time (GMT)
User entered 'INCLUSION CRITERIA 3. LOSS OF TASTE AND SMELL PERSISTS, THIS WILL AFFECT ABILITY FOR MONITORING COVID-19 SYMPTOMS.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 16:20:26
User opened query 'Per CDM: Please be aware that "Inclusion Criteria 3" cannot be entered. Please provide here actual reason why subject discontinued dosing. "Visit 2" Exposure form states that was physician decision because of taste or smell lost and AE is entered. However, AE is entered but no "Investigation product withdrawn". Please review all the necessary forms and update accordingly. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 11:31:02
User entered 'Inclusion Criteria 3'	Karol Moore (b) (4) (b) (4)	15 Dec 2020 21:15:09