

US3862050 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:30:28

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US3862050

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Participant ID

US3862050

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

US3862050

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input 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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:35:51

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Date of Informed Consent (<i>dd MMM yyyy</i>)	24 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:35:51

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:35:51

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Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN JAN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:32 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 12:32
Height (<i>xxx.x</i>)	73.7 in
Weight (<i>xxx.x</i>)	216.6 lb
BMI (<i>xxx.x</i>)	28.09528 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:35:51

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:35:51

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☒ No ☐

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:35:51

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 106942

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

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)	24 AUG 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 12:32
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

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)	24 AUG 2020
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:24
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 13:53 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 13:53

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

13:08 (24 HR)

Collection date and time (derived)

24 AUG 2020 13:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:47	24 AUG 2020 12:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:27

PC Open Date & Time

24 AUG 2020 14:13

PC Close Date & Time

24 AUG 2020 16:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	24 AUG 2020 22:40
PC Open Date & Time	24 AUG 2020 17:38
PC Close Date & Time	25 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

26 AUG 2020 03:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

27 AUG 2020 08:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

28 AUG 2020 07:38

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 11:15

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

102.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 23:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

31 AUG 2020 10:04

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

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

98.5 °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

01 SEP 2020 07:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 14:29

PC Open Date & Time

24 AUG 2020 14:13

PC Close Date & Time

24 AUG 2020 16:43

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 22:41

PC Open Date & Time

24 AUG 2020 17:38

PC Close Date & Time

25 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 03:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 08:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 07:38

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

29 AUG 2020 11:15

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 23:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

31 AUG 2020 10:04

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 14:30
PC Open Date & Time	24 AUG 2020 14:13
PC Close Date & Time	24 AUG 2020 16:43

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 22:41
PC Open Date & Time	24 AUG 2020 17:38
PC Close Date & Time	25 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 03:11
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 08:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 07:39
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

		Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 11:16	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 23:27
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 10:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

01 SEP 2020 07:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 07:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

01 SEP 2020 07:04

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 SEP 2020 07:04

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

PC Time stamp 01 SEP 2020 07:05

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 07:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3862050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:54:50

Generated On: 12 Aug 2021 13:30:28

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:54:50

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:54:50

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:54:49

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☒
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3862050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:54:49

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Mar 2021 15:54:49

Generated On: 12 Aug 2021 13:30:28

Collection date (dd MMM yyyy)

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

US3862050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:51

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 11:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3862050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

11:59 (24 HR)

Collection date and time (derived)

26 OCT 2020 11:59

US3862050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:35:52

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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 <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"/>

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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 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"/>

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 124

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

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27 DEC 2020 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

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03 JAN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

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10 JAN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 152

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 173

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

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17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 12:50:12

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 11:17:19

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 229

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3862050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:30:28

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		02 MAR 2021 16:12:25

US3862050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:26:43

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:26:43

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

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

Visit date (dd MMM yyyy)	02 APR 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
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US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 13:59:02

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 APR 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 11:33
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 APR 2021

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

US3862050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 APR 2021

Collection time (00:00-23:59)

11:42 (24 HR)

Collection date and time (derived)

02 APR 2021 11:42

US3862050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 13:59:01

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Date of Contact	1 SEP 2020
Time of Contact	14:25
Date and Time of Contact (derived)	1 SEP 2020 14:25
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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"/>

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	102.4 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.2 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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"/>

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 AUG 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	99.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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"/>

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	1 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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 ☐

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	2 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	3 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	4 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	99 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	5 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	6 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	7 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	8 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	9 SEP 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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 ☐

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	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	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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 ☐

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Symptom Day

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Date of Visit	1 SEP 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	1 SEP 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)	1

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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EAB) (1725)

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US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3862050

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	03 SEP 2020
Day 5	Yes	05 SEP 2020
Day 7	Yes	07 SEP 2020
Day 9	Yes	09 SEP 2020
Day 14	Yes	14 SEP 2020
Day 21	Yes	21 SEP 2020
Day 28	Yes	01 OCT 2020

US3862050

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SICKD1

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:25
Height (xxx.x)	73.7 in
Weight (xxx.x)	216.6 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3862050

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

01 SEP 2020

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SICKD28

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 11:58
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 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)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

01 OCT 2020

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	25 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	25 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

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)	25 FEB 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 14:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

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)	25 FEB 2021
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 16:08
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 15:38 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 15:38

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

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

14:17 (24 HR)

Collection date and time (derived)

25 FEB 2021 14:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00 - 23:59)

14:15

Collection Date and Time (derived)

25 FEB 2021 14:15

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:40

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3862050

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:33:01

Generated On: 12 Aug 2021 13:30:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 18:33:01

Generated On: 12 Aug 2021 13:30:28

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)	02 APR 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 11:33
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 18:33:01

Generated On: 12 Aug 2021 13:30:28

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)	02 APR 2021
Time of assessment (00:00-23:59)	13:04 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 13:04
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3862050

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:33:00

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3862050

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 18:33:00

Generated On: 12 Aug 2021 13:30:28

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 02 APR 2021

What was the treatment time? (00:00-23:59) 12:34 (24 HR)

Treatment Date and Time (derived) 02 APR 2021 12:34

Which arm was used to give treatment? Left Arm ☒
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3862050

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:33:00

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 21:41:38

Generated On: 12 Aug 2021 13:30:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862050

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 21:41:38

Generated On: 12 Aug 2021 13:30:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862050

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3862050

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3862050

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3862050

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3862050

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:30:28

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3862050

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:12:51

Generated On: 12 Aug 2021 13:30:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

AEID	USA-US121-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	29 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)	11 SEP 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"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

~~SUBMITTED TO FDA~~

2. SUBJECT'S PARONYCHIA

POSITIVE FOR COVID-19 ON
28-AUG-2020

3. 29-AUG-2020 (DAY 6):
TEMPERATURE 102.4°F WITH
“MILD” CHILLS, FATIGUE, SORE
THROAT. TOOK NYQUIL 2-3
TEASPOONS AND TYLENOL
LIQUID 2-3 TEASPOONS

4. 30-AUG-2020 (DAY 7):
TEMPERATURE 100.2°F WITH
“MILD” CHILLS, FATIGUE,
HEADACHE, BODY ACHES
TOOK TYLENOL 3 TEASPOONS

5. 31-AUG-2020 (DAY 8):
MORNING TEMPERATURE
99.2°F AFTERNOON
TEMPERATURE 98.5°F
STILL WITH “MILD” BODY
ACHES, REST OF SYMPTOMS
SUBSIDED

01 SEP 2020: MORNING
TEMPERATURE: 97.4°F, STILL
WITH “MILD” BODY ACHES.
DENIES ANY OTHER
SYMPTOMS

8:00 AM HAD RAPID TESTING
AT WALGREENS

10:30 AM RECEIVED PHONE
CALL—TESTED POSITIVE FOR
SARS COV-2
STARTED QUARANTINE TODAY
ILLNESS VISIT:
14:25:

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

VITAL SIGNS: BP 144/89, P 71, R
18, T 98.6°F, O2 SATURATION
98% (ROOM AIR)
PE: NOT ACUTELY ILL, LUNGS:
BILATERAL- CLEAR ON
AUSCULTATION ENT: NO
SIGNIFICANT FINDINGS
LAB WORK DONE: NP SWAB
COLLECTIONS DONE (PCR FOR
SARS-COV-2) AND BIOFIRE RPS
FOR OTHER VIRUSES
SUBJECT WAS INFORMED,
GIVEN EXPLANATIONS AND
INSTRUCTIONS ON THE
FOLLOWING:
1) TELEMEDICINE OR PHONE
CALL DAILY X 14DAYS OR
UNTIL SYMPTOMS RESOLVE,
SUBJECT PREFERS PHONE
CALLS
2) DAILY
CHECKING/MONITORING OF
ORAL TEMPERATURE AND O2
SATURATION LEVEL
3) HOME SALIVA
COLLECTIONS: DAY 3-DAY 21
4) ADVISED TO FOLLOW UP
WITH PCP, SEEK IMMEDIATE
MEDICAL HELP FOR SEVERE
RESPIRATORY SYMPTOMS,
SHORTNESS OF BREATH, RAPID
HEART RATE, O2 SATURATION
≤ 93%, SEVERE CHILLS,
TEMPERATURE ≥100.4.
5) SUBJECT VERBALIZED

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

<hr/>		UNDERSTANDING AND AGREEMENT OF PLAN.
<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)		
<hr/>		

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	31 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)	01 SEP 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)

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US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 14:21:40

Generated On: 12 Aug 2021 13:30:28

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Name of Medication TYLENOL LIQUID

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

Dose per administration 2-3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify TEASPOONS

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	30 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Name of Medication NYQUIL COLD AND FLU
(ACETAMINOPHEN 500MG,
DOXYLAMINE SUCCINATE 6.25
MG, DEXTROMETHORPHAN
HBR 15MG)

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

Dose per administration 2-3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify TEASPOONS

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:09:04

Generated On: 12 Aug 2021 13:30:28

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3862050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 12 Aug 2021 13:30:28

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	True
Demographics	True
Enrollment	True
Inclusion/Exclusion Criteria Summary	True
Inclusion/Exclusion Criteria	True
Medical History Summary	True
Medical History	True
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
Randomization	True
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	True
COVID Diagnostic Test	True
Symptom Log	True
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	True
COVID-19 Severity Assessment	True
COVID-19 Contact	True
Risk of Exposure	True
Safety Call	True
Dosing Discontinuation	True

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	21 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	STILL ON CONVALESCENT PERIOD
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	True
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	True
Sponsor hold due to COVID-19	False
Participant decision	False

US3862050

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 14:09:05

Generated On: 12 Aug 2021 13:30:28

Date of dosing discontinuation (dd MMM yyyy) 1 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#1

US3862050

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:30:28

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

SAEID	USA-US121-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

SAEID	USA-US121-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/SEP/2020 12:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

SAEID	USA-US121-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/OCT/2020 11:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 14:10:39

Generated On: 12 Aug 2021 13:30:28

SAEID	USA-US121-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3862050 (Prod: Baylor College of Medicine)

US3862050

Form: Participant Creation

Generated On: 12 Aug 2021 13:30:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'US3862050'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:25

US3862050

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:10

US3862050

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:26

US3862050

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:10

US3862050

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'SCRN'	System	24 Aug 2020 18:34:10

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:27

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '50'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User entered 'YEARS'	System	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User entered '50'	System	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Male (M)'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'I'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:30:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:11:59

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User entered 'Aug 2020'	System	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User entered '2020'	System	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Amendment 2 (2)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Sandra Francisco (b) (4) (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Sandra Francisco (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:34:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 18:34:24
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	24 Aug 2020 18:34:24
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 18:34:21
User entered empty.	Sandra Francisco (b) (4)	24 Aug 2020 18:34:21

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:26

US3862050

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:30:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User entered 'I'	System	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:30:28

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:09
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:30:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:22:20

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:25:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:25:39
Data point term sent to Coder	System	24 Aug 2020 19:24:31
User entered 'Gastroesophageal reflux disease'	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'UN Jan 2016'	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'Jan 2016'	System	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered '2016'	System	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered empty.	System	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:30:28

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered empty.	System	24 Aug 2020 19:23:56

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40
	(b) (4)	

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '12:32'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered '24 Aug 2020 12:32'	System	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '73.7' in	Chanei Henry (b) (4)	24 Aug 2020 19:13:40
DataPoint set to visible.	(b) (4) System	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '216.6' lb	Chanei Henry (b) (4)	24 Aug 2020 19:13:40
DataPoint set to visible.	(b) (4) System	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
Amendment Manager: User entered '28.09528'	System	17 Sep 2020 00:21:41
User entered '28.1'	System	24 Aug 2020 19:13:40
DataPoint set to visible.	System	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'kg/m2'	System	24 Aug 2020 19:13:40
DataPoint set to visible.	System	24 Aug 2020 18:34:30

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:15
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' answered with 'UPDATED' (Site from DM).	Shetel Anassi (b) (4)	23 Nov 2020 16:30:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:30:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:30:04
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:48:54
User entered '97.8' F	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:12
User entered 'Other (Other)'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:12
User entered 'Temporal'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:04
User entered '69'	(b) (4)	
	Chanei Henry (b) (4)	24 Aug 2020 19:13:40
	(b) (4)	

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'bpm'	System	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:04
User entered '15'	(b) (4)	
	Chanei Henry (b) (4)	24 Aug 2020 19:13:40
	(b) (4)	

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'breaths/min'	System	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:04
User entered '138'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'mmHg'	System	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:30:04
User entered '78'	Chanei Henry (b) (4)	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User entered 'mmHg'	System	24 Aug 2020 19:13:40

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32

US3862050

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32

US3862050

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:39

US3862050

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:14:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 13:55:37
User entered '24 Aug 2020'	Sandra Francisco (b) (4) (b) (4)	24 Aug 2020 18:34:39

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

US3862050

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13
	(b) (4)	

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'I'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:30:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:05:32
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:15:13

US3862050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:54

US3862050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:54

US3862050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[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 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4)	24 Aug 2020 18:34:54

US3862050

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'VISIT1'	System	24 Aug 2020 18:34:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:28

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '106942'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:28

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:24:28

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

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 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

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 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:15:54

US3862050

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:30:28

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Carrie Kibler (b) (4)	22 Sep 2020 17:48:45
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:40:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:42:55

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:06
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' answered with 'UPDATED' (Site from DM).	Shetel Anassi (b) (4)	23 Nov 2020 16:50:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:50:14
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:15:39
User entered '73.7' in	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:50:14
User entered '216.6' lb	(b) (4)	
	Chanei Henry (b) (4)	24 Aug 2020 19:09:49
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:06
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' answered with 'UPDATED' (Site from DM).	Shetel Anassi (b) (4)	23 Nov 2020 16:50:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:50:14
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:15:39
User entered '73.7' in	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:50:14
User entered '216.6' lb	(b) (4)	
	Chanei Henry (b) (4)	24 Aug 2020 19:09:49
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User accepted default value 'Pre-Dose (PREDOSE)'	Chaneí Henry (b) (4) (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '12:32'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '24 Aug 2020 12:32'	System	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '97.8' F	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Other (Other)'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Temporal'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '69'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'bpm'	System	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '15'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'breaths/min'	System	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '138'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'mmHg'	System	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '78'	Chanei Henry (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'mmHg'	System	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:06
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' answered with 'UPDATED' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 16:50:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 16:50:14
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for HEIGHT and WEIGHT as per CCGs v2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:15:39
User entered '73.7' in	Chanei Henry (b) (4) (b) (4)	24 Aug 2020 19:09:49

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	23 Nov 2020 16:50:14
User entered '216.6' lb	(b) (4)	
	Chanei Henry (b) (4)	24 Aug 2020 19:09:49
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User accepted default value 'Post-Dose (POSTDOSE)'	Chanei Henry (b) (4) (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '14:24'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '24 Aug 2020 14:24'	System	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '97.8' F	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Other (Other)'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Temporal'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '69'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'bpm'	System	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '14'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'breaths/min'	System	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '133'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'mmHg'	System	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '81'	Chanei Henry (b) (4)	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'mmHg'	System	24 Aug 2020 19:34:13

US3862050

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	24 Aug 2020 18:35:02

US3862050

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Sandra Francisco (b) (4)	24 Aug 2020 18:35:02

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

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 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:07:46
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:07:46
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '13:53'	Chanei Henry (b) (4)	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '24 Aug 2020 13:53'	System	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Left Arm (LEFT ARM)'	Chanei Henry (b) (4)	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'ONCE'	System	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 19:07:46

US3862050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:10:17

US3862050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:10:17
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '13:08'	Chanei Henry (b) (4)	24 Aug 2020 19:10:17

US3862050

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '24 Aug 2020 13:08'	System	24 Aug 2020 19:10:17

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '24 Aug 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:10:43
	(b) (4)	

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chanci Henry (b) (4) (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '12:47'	Chanei Henry (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '24 Aug 2020 12:47'	System	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chaneí Henry (b) (4) (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered empty.	System	24 Aug 2020 19:10:43

US3862050

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:10:52

US3862050

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'I'	System	24 Aug 2020 19:10:52

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:27:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'de3c24f6-e907-4694-adde-ed08261b41f0'	System	24 Aug 2020 19:27:54
User entered 'Yes (Y)'	System	24 Aug 2020 19:27:54

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:27:22', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'de3c24f6-e907-4694-adde-ed08261b41f0'	System	24 Aug 2020 19:27:54
User entered '97.8'	System	24 Aug 2020 19:27:54

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:27:27', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'de3c24f6-e907-4694-adde-ed08261b41f0'	System	24 Aug 2020 19:27:54
User entered 'No (N)'	System	24 Aug 2020 19:27:54

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:27:49', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'de3c24f6-e907-4694-adde-ed08261b41f0'	System	24 Aug 2020 19:27:54
User entered '24 Aug 2020 14:27'	System	24 Aug 2020 19:27:54

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 16:43'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:40:34', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '914be1af-655e-4ee7-9c67-f0baacaab6d0'	System	25 Aug 2020 03:40:52
User entered 'Yes (Y)'	System	25 Aug 2020 03:40:52

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:40:42', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '914be1af-655e-4ee7-9c67-f0baacaab6d0'	System	25 Aug 2020 03:40:52
User entered '98.0'	System	25 Aug 2020 03:40:52

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:40:46', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '914be1af-655e-4ee7-9c67-f0baacaab6d0'	System	25 Aug 2020 03:40:52
User entered 'No (N)'	System	25 Aug 2020 03:40:52

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:40:49', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '914be1af-655e-4ee7-9c67-f0baacaab6d0'	System	25 Aug 2020 03:40:52
User entered '24 Aug 2020 22:40'	System	25 Aug 2020 03:40:52

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 17:38'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 2'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:09:40', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'c8357dd3-fbb4-4aec-b130-c70937d7f585'	System	26 Aug 2020 08:10:07
User entered 'Yes (Y)'	System	26 Aug 2020 08:10:07

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:09:50', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'c8357dd3-fbb4-4aec-b130-c70937d7f585'	System	26 Aug 2020 08:10:07
User entered '97.4'	System	26 Aug 2020 08:10:07

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:09:56', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'c8357dd3-fbb4-4aec-b130-c70937d7f585'	System	26 Aug 2020 08:10:07
User entered 'No (N)'	System	26 Aug 2020 08:10:07

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:02', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'c8357dd3-fbb4-4aec-b130-c70937d7f585'	System	26 Aug 2020 08:10:07
User entered '26 Aug 2020 03:10'	System	26 Aug 2020 08:10:07

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 3'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:18:53', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'effd9ede-d263-40a6-a8d0-9dfc87da5256'	System	27 Aug 2020 13:19:18
User entered 'Yes (Y)'	System	27 Aug 2020 13:19:18

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'effd9ede-d263-40a6-a8d0-9dfc87da5256'	System	27 Aug 2020 13:19:18
User entered '97.9'	System	27 Aug 2020 13:19:18

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:13', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'effd9ede-d263-40a6-a8d0-9dfc87da5256'	System	27 Aug 2020 13:19:18
User entered 'No (N)'	System	27 Aug 2020 13:19:18

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:16', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'effd9ede-d263-40a6-a8d0-9dfc87da5256'	System	27 Aug 2020 13:19:18
User entered '27 Aug 2020 08:19'	System	27 Aug 2020 13:19:18

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 4'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '46fcc8cf-fd6a-4c36-90da-fd902c8b3c88'	System	28 Aug 2020 12:38:25
User entered 'Yes (Y)'	System	28 Aug 2020 12:38:25

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '46fcc8cf-fd6a-4c36-90da-fd902c8b3c88'	System	28 Aug 2020 12:38:25
User entered '97.4'	System	28 Aug 2020 12:38:25

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:19', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '46fcc8cf-fd6a-4c36-90da-fd902c8b3c88'	System	28 Aug 2020 12:38:25
User entered 'No (N)'	System	28 Aug 2020 12:38:25

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:22', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '46fcc8cf-fd6a-4c36-90da-fd902c8b3c88'	System	28 Aug 2020 12:38:25
User entered '28 Aug 2020 07:38'	System	28 Aug 2020 12:38:25

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 5'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:14:49', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '20d428c3-ef02-4a5f-9dfe-c53e31fbe677'	System	29 Aug 2020 16:15:12
User entered 'Yes (Y)'	System	29 Aug 2020 16:15:12

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:14:57', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '20d428c3-ef02-4a5f-9dfe-c53e31fbe677'	System	29 Aug 2020 16:15:12
User entered '97.2'	System	29 Aug 2020 16:15:12

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:04', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '20d428c3-ef02-4a5f-9dfe-c53e31fbe677'	System	29 Aug 2020 16:15:12
User entered 'No (N)'	System	29 Aug 2020 16:15:12

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:09', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '20d428c3-ef02-4a5f-9dfe-c53e31fbe677'	System	29 Aug 2020 16:15:12
User entered '29 Aug 2020 11:15'	System	29 Aug 2020 16:15:12

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 6'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:24:31', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac'	System	30 Aug 2020 04:25:14
User entered 'Yes (Y)'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:24:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac' User entered '102.4'	System	30 Aug 2020 04:25:14
	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:24:53', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac'	System	30 Aug 2020 04:25:14
User entered 'Yes (Y)'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication entered' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:49:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac'	Chanei Henry (b) (4)	08 Sep 2020 22:57:50
User entered '1'	(b) (4)	
	System	30 Aug 2020 04:25:14
	System	30 Aug 2020 04:25:14
	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac'	System	30 Aug 2020 04:25:14
User entered '0'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:10', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'f1e337d7-be88-4599-ba76-476743647aac'	System	30 Aug 2020 04:25:14
User entered '29 Aug 2020 23:25'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 7'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:03:55', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db'	System	31 Aug 2020 15:05:38
User entered 'Yes (Y)'	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:01', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db' User entered '100.2'	System	31 Aug 2020 15:05:38
	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:05', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db'	System	31 Aug 2020 15:05:38
User entered 'Yes (Y)'	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication entered' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:49:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db'	Chanei Henry (b) (4)	08 Sep 2020 22:58:13
User entered '1'	(b) (4)	
	System	31 Aug 2020 15:05:38
	System	31 Aug 2020 15:05:38
	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db' User entered '0'	System	31 Aug 2020 15:05:38
	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:18', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3aa3eb87-75db-4292-8f59-0079abf283db'	System	31 Aug 2020 15:05:38
User entered '31 Aug 2020 10:04'	System	31 Aug 2020 15:05:38

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:25:14
User entered 'Day 8'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:03:51', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'adbd9d3a-659f-4a06-b726-251456af39d1'	System	01 Sep 2020 12:04:10
User entered 'Yes (Y)'	System	01 Sep 2020 12:04:10

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:03:57', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'adbd9d3a-659f-4a06-b726-251456af39d1'	System	01 Sep 2020 12:04:10
User entered '98.5'	System	01 Sep 2020 12:04:10

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:02', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'adbd9d3a-659f-4a06-b726-251456af39d1'	System	01 Sep 2020 12:04:10
User entered 'No (N)'	System	01 Sep 2020 12:04:10

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:05', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'adbd9d3a-659f-4a06-b726-251456af39d1'	System	01 Sep 2020 12:04:10
User entered '01 Sep 2020 07:04'	System	01 Sep 2020 12:04:10

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:28:11', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '460521a7-4402-4744-b82a-b53131df836a'	System	24 Aug 2020 19:29:57
User entered 'None (1)'	System	24 Aug 2020 19:29:57

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:28:16', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '460521a7-4402-4744-b82a-b53131df836a'	System	24 Aug 2020 19:29:57
User entered 'No (N)'	System	24 Aug 2020 19:29:57

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:28:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '460521a7-4402-4744-b82a-b53131df836a'	System	24 Aug 2020 19:29:57
User entered 'No (N)'	System	24 Aug 2020 19:29:57

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:28:30', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '460521a7-4402-4744-b82a-b53131df836a'	System	24 Aug 2020 19:29:57
User entered 'None (1)'	System	24 Aug 2020 19:29:57

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:29:55', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '460521a7-4402-4744-b82a-b53131df836a'	System	24 Aug 2020 19:29:57
User entered '24 Aug 2020 14:29'	System	24 Aug 2020 19:29:57

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 16:43'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:40:56', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'e68bc29b-396d-4de7-aa20-a15f705a4b1d'	System	25 Aug 2020 03:41:18
User entered 'None (1)'	System	25 Aug 2020 03:41:18

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:00', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'e68bc29b-396d-4de7-aa20-a15f705a4b1d'	System	25 Aug 2020 03:41:18
User entered 'No (N)'	System	25 Aug 2020 03:41:18

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:06', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'e68bc29b-396d-4de7-aa20-a15f705a4b1d'	System	25 Aug 2020 03:41:18
User entered 'No (N)'	System	25 Aug 2020 03:41:18

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:09', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'e68bc29b-396d-4de7-aa20-a15f705a4b1d'	System	25 Aug 2020 03:41:18
User entered 'None (1)'	System	25 Aug 2020 03:41:18

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:12', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'e68bc29b-396d-4de7-aa20-a15f705a4b1d'	System	25 Aug 2020 03:41:18
User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:18

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 17:38'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 2'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:27', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2cd3131b-0438-4d7a-9e6a-e2374e04396e'	System	26 Aug 2020 08:10:44
User entered 'None (1)'	System	26 Aug 2020 08:10:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:31', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2cd3131b-0438-4d7a-9e6a-e2374e04396e'	System	26 Aug 2020 08:10:44
User entered 'No (N)'	System	26 Aug 2020 08:10:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:35', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2cd3131b-0438-4d7a-9e6a-e2374e04396e'	System	26 Aug 2020 08:10:44
User entered 'No (N)'	System	26 Aug 2020 08:10:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2cd3131b-0438-4d7a-9e6a-e2374e04396e'	System	26 Aug 2020 08:10:44
User entered 'None (1)'	System	26 Aug 2020 08:10:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:42', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2cd3131b-0438-4d7a-9e6a-e2374e04396e'	System	26 Aug 2020 08:10:44
User entered '26 Aug 2020 03:10'	System	26 Aug 2020 08:10:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 3'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:22', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'acdb77c4-141e-4f96-a025-0a06cf1119c3'	System	27 Aug 2020 13:19:36
User entered 'None (1)'	System	27 Aug 2020 13:19:36

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:25', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'acdb77c4-141e-4f96-a025-0a06cf1119c3'	System	27 Aug 2020 13:19:36
User entered 'No (N)'	System	27 Aug 2020 13:19:36

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:28', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'acdb77c4-141e-4f96-a025-0a06cf1119c3'	System	27 Aug 2020 13:19:36
User entered 'No (N)'	System	27 Aug 2020 13:19:36

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:31', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'acdb77c4-141e-4f96-a025-0a06cf1119c3'	System	27 Aug 2020 13:19:36
User entered 'None (1)'	System	27 Aug 2020 13:19:36

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:34', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'acdb77c4-141e-4f96-a025-0a06cf1119c3'	System	27 Aug 2020 13:19:36
User entered '27 Aug 2020 08:19'	System	27 Aug 2020 13:19:36

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 4'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:29', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6e1f930e-1209-4187-be4c-add6dd1c46ae'	System	28 Aug 2020 12:38:44
User entered 'None (1)'	System	28 Aug 2020 12:38:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:32', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6e1f930e-1209-4187-be4c-add6dd1c46ae'	System	28 Aug 2020 12:38:44
User entered 'No (N)'	System	28 Aug 2020 12:38:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:34', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6e1f930e-1209-4187-be4c-add6dd1c46ae'	System	28 Aug 2020 12:38:44
User entered 'No (N)'	System	28 Aug 2020 12:38:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6e1f930e-1209-4187-be4c-add6dd1c46ae'	System	28 Aug 2020 12:38:44
User entered 'None (1)'	System	28 Aug 2020 12:38:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:42', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6e1f930e-1209-4187-be4c-add6dd1c46ae'	System	28 Aug 2020 12:38:44
User entered '28 Aug 2020 07:38'	System	28 Aug 2020 12:38:44

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 5'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:15', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '500010e0-a0e9-4714-995e-40d7fe39c550'	System	29 Aug 2020 16:15:29
User entered 'None (1)'	System	29 Aug 2020 16:15:29

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:17', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '500010e0-a0e9-4714-995e-40d7fe39c550'	System	29 Aug 2020 16:15:29
User entered 'No (N)'	System	29 Aug 2020 16:15:29

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:20', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '500010e0-a0e9-4714-995e-40d7fe39c550'	System	29 Aug 2020 16:15:29
User entered 'No (N)'	System	29 Aug 2020 16:15:29

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:24', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '500010e0-a0e9-4714-995e-40d7fe39c550'	System	29 Aug 2020 16:15:29
User entered 'None (1)'	System	29 Aug 2020 16:15:29

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:27', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '500010e0-a0e9-4714-995e-40d7fe39c550'	System	29 Aug 2020 16:15:29
User entered '29 Aug 2020 11:15'	System	29 Aug 2020 16:15:29

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 6'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:17', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '770d1b93-c181-4f8e-8788-d2dfeac828b5'	System	30 Aug 2020 04:25:52
User entered 'None (1)'	System	30 Aug 2020 04:25:52

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '770d1b93-c181-4f8e-8788-d2dfeac828b5'	System	30 Aug 2020 04:25:52
User entered 'No (N)'	System	30 Aug 2020 04:25:52

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:35', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '770d1b93-c181-4f8e-8788-d2dfeac828b5'	System	30 Aug 2020 04:25:52
User entered 'No (N)'	System	30 Aug 2020 04:25:52

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:46', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '770d1b93-c181-4f8e-8788-d2dfeac828b5'	System	30 Aug 2020 04:25:52
User entered 'None (1)'	System	30 Aug 2020 04:25:52

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:25:48', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '770d1b93-c181-4f8e-8788-d2dfeac828b5'	System	30 Aug 2020 04:25:52
User entered '29 Aug 2020 23:25'	System	30 Aug 2020 04:25:52

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 7'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:26', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6c510eb5-a270-4ac9-866c-28fa0bb05abc'	System	31 Aug 2020 15:05:49
User entered 'None (1)'	System	31 Aug 2020 15:05:49

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:33', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6c510eb5-a270-4ac9-866c-28fa0bb05abc'	System	31 Aug 2020 15:05:49
User entered 'No (N)'	System	31 Aug 2020 15:05:49

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6c510eb5-a270-4ac9-866c-28fa0bb05abc'	System	31 Aug 2020 15:05:49
User entered 'No (N)'	System	31 Aug 2020 15:05:49

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:43', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6c510eb5-a270-4ac9-866c-28fa0bb05abc'	System	31 Aug 2020 15:05:49
User entered 'None (1)'	System	31 Aug 2020 15:05:49

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:04:46', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '6c510eb5-a270-4ac9-866c-28fa0bb05abc'	System	31 Aug 2020 15:05:49
User entered '31 Aug 2020 10:04'	System	31 Aug 2020 15:05:49

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:03', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee-4f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:08', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:13', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:19', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:25', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:29', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'None (0)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:36', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered 'No (N)'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T14:30:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f0eeb51-fee4-f90-a663-358513f3a49e'	System	24 Aug 2020 19:30:45
User entered '24 Aug 2020 14:30'	System	24 Aug 2020 19:30:45

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 14:13'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 16:43'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:18', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:24', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:27', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:30', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:32', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'None (0)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:37', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered 'No (N)'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-24T22:41:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b8161f53-3cf4-4e86-a8e7-d865f10c9ca2'	System	25 Aug 2020 03:41:42
User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:42

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '24 Aug 2020 17:38'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 2'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:52', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:55', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:10:58', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:11:04', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:11:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:11:11', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'None (0)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:11:18', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered 'No (N)'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-26T03:11:20', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '8274b510-443a-42ae-86c7-e351062085b1'	System	26 Aug 2020 08:11:24
User entered '26 Aug 2020 03:11'	System	26 Aug 2020 08:11:24

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 3'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:40', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:43', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:46', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:50', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:52', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:19:55', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'None (0)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:20:01', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered 'No (N)'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-27T08:20:03', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '80f05dd1-518b-437f-bcf6-515630036269'	System	27 Aug 2020 13:20:04
User entered '27 Aug 2020 08:20'	System	27 Aug 2020 13:20:04

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 4'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:48', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:55', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:38:58', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:39:02', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:39:05', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:39:08', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'None (0)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:39:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered 'No (N)'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-28T07:39:17', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '1f5aeb2a-05c1-4d42-81d4-5abc573b6e00'	System	28 Aug 2020 12:39:20
User entered '28 Aug 2020 07:39'	System	28 Aug 2020 12:39:20

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 5'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:41', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered 'None (0)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:15:49', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered 'None (0)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:02', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a' User entered 'None (0)'	System	29 Aug 2020 16:16:29
	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:04', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a' User entered 'None (0)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:10', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered 'None (0)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered 'None (0)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered 'Yes (Y)'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T11:16:25', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '41f77376-abe0-41d4-8e01-9d756a97226a'	System	29 Aug 2020 16:16:29
User entered '29 Aug 2020 11:16'	System	29 Aug 2020 16:16:29

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 6'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:26:09', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'None (0)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:26:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'Some interference with activity (2)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:26:29', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'Some interference with activity (2)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:27:13', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'Some interference with activity (2)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:27:19', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'None (0)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:27:27', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'Some interference with activity not requiring medical attention (2)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:27:39', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered 'No (N)'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-29T23:27:43', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '9aa7a174-4f47-41e6-904f-9a2bf22eb332'	System	30 Aug 2020 04:27:46
User entered '29 Aug 2020 23:27'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 7'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:28', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:35', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'Some interference with activity (2)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:40', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'Some interference with activity (2)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:47', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'Some interference with activity (2)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:51', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'None (0)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:05:54', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'Some interference with activity not requiring medical attention (2)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:06:01', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered 'No (N)'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-08-31T10:06:03', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '7bacaa51-e2ca-4a73-a722-8edf793a4b14'	System	31 Aug 2020 15:06:07
User entered '31 Aug 2020 10:06'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	31 Aug 2020 15:06:07
User entered 'Day 8'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2e7bf7de-8021-4b75-80c9-978bb09d867f' User entered 'None (0)'	System	01 Sep 2020 12:04:25
	System	01 Sep 2020 12:04:25

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:21', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '2e7bf7de-8021-4b75-80c9-978bb09d867f' User entered '01 Sep 2020 07:04'	System	01 Sep 2020 12:04:25
	System	01 Sep 2020 12:04:25

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:27:46
User entered 'Day 8'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:29', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'ab0a1ba6-5053-4a60-90ac-29cccb8b7841'	System	01 Sep 2020 12:04:35
User entered 'No interference with activity (1)'	System	01 Sep 2020 12:04:35

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:33', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'ab0a1ba6-5053-4a60-90ac-29cccb8b7841'	System	01 Sep 2020 12:04:35
User entered '01 Sep 2020 07:04'	System	01 Sep 2020 12:04:35

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	31 Aug 2020 15:06:07
User entered 'Day 9'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T21:04:48', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'dc2dec88-31a8-4163-9ebc-73eb63769fca'	System	02 Sep 2020 02:04:54
User entered 'None (0)'	System	02 Sep 2020 02:04:54

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T21:04:51', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'dc2dec88-31a8-4163-9ebc-73eb63769fca'	System	02 Sep 2020 02:04:54
User entered '01 Sep 2020 21:04'	System	02 Sep 2020 02:04:54

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:06:07

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:27:46
User entered 'Day 8'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:42', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '53ff7513-55c4-4f72-8918-cab3371f8b39'	System	01 Sep 2020 12:04:47
User entered 'None (0)'	System	01 Sep 2020 12:04:47

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:45', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '53ff7513-55c4-4f72-8918-cab3371f8b39'	System	01 Sep 2020 12:04:47
User entered '01 Sep 2020 07:04'	System	01 Sep 2020 12:04:47

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:27:46
User entered 'Day 8'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:51', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '65489564-af60-4f09-b606-e2fffa5a3223'	System	01 Sep 2020 12:04:56
User entered 'None (0)'	System	01 Sep 2020 12:04:56

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:04:54', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '65489564-af60-4f09-b606-e2fffa5a3223'	System	01 Sep 2020 12:04:56
User entered '01 Sep 2020 07:04'	System	01 Sep 2020 12:04:56

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:27:46
User entered 'Day 8'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:05:00', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'aed049a5-51dd-46ca-905c-a71c306a1a4b'	System	01 Sep 2020 12:05:07
User entered 'None (0)'	System	01 Sep 2020 12:05:07

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:27:46

US3862050

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:05:03', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'aed049a5-51dd-46ca-905c-a71c306a1a4b'	System	01 Sep 2020 12:05:07
User entered '01 Sep 2020 07:05'	System	01 Sep 2020 12:05:07

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
Data entry locked.	System	30 Aug 2020 04:25:14
User entered 'Day 8'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

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 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:05:10', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b59eacbe-bf88-4819-8945-57eb8697ef4e'	System	01 Sep 2020 12:05:18
User entered 'No (N)'	System	01 Sep 2020 12:05:18

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2020-09-01T07:05:14', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: 'b59eacbe-bf88-4819-8945-57eb8697ef4e'	System	01 Sep 2020 12:05:18
User entered '01 Sep 2020 07:05'	System	01 Sep 2020 12:05:18

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 04:25:14

US3862050

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:30:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:03:21
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 04:25:14

US3862050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:14:21

US3862050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '31 Aug 2020'	Coni Cheesman (b) (4)	31 Aug 2020 23:14:21

US3862050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4)	31 Aug 2020 23:14:21

US3862050

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:14:21

US3862050

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	01 Sep 2020 23:41:40

US3862050

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered 'I'	System	01 Sep 2020 23:41:40

US3862050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	08 Sep 2020 22:24:19

US3862050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '07 Sep 2020' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	10 Nov 2020 14:16:27
User entered '7 Sep 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	05 Oct 2020 21:16:07
User entered '8 Sep 2020'	Carrie Kibler (b) (4)	08 Sep 2020 22:24:19

US3862050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	08 Sep 2020 22:24:19

US3862050

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	08 Sep 2020 22:24:19

US3862050

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	08 Sep 2020 22:24:23

US3862050

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:15
User entered '1'	System	08 Sep 2020 22:24:23

US3862050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:56:47

US3862050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '14 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:56:47

US3862050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:56:47

US3862050

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:56:47
	(b) (4)	

US3862050

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:57:00

US3862050

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:20
User entered '1'	System	14 Sep 2020 22:57:00

US3862050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4)	
	Chanei Henry (b) (4)	24 Mar 2021 23:50:50
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:50
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[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 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	Chanei Henry (b) (4)	24 Mar 2021 23:50:50

US3862050

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'VISIT2'	System	24 Mar 2021 23:50:50

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User accepted default value 'Pre-Dose (PREDOSE)'	Chaneí Henry (b) (4)	24 Mar 2021 23:50:59
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User accepted default value 'Post-Dose (POSTDOSE)'	Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4)	24 Mar 2021 23:50:59
	Chanei Henry (b) (4)	
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:50:59

US3862050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Mar 2021 23:51:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 23:51:09
User entered 'No (N)' reason for change: Data Entry Error	Chanei Henry (b) (4)	24 Mar 2021 23:51:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Mar 2021 23:51:06
User entered empty.	System	24 Mar 2021 23:51:06
	Chanei Henry (b) (4)	24 Mar 2021 23:51:06
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:51:06

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
Query 'Per CDM: Please complete all required V2D29 forms. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:47:05
User opened query 'Per CDM: Please complete all required V2D29 forms. Thank you.' (Site from DM).		19 Nov 2020 10:46:24
User entered 'No (N)'	Chanei Henry (b) (4)	22 Oct 2020 22:54:08
	(b) (4)	

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Confirmed COVID-19 (COVID)'	Chanei Henry (b) (4)	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

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 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Chanei Henry (b) (4)	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	22 Oct 2020 22:54:08

US3862050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:11

US3862050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:11

US3862050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:11

US3862050

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:52:11

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chaneí Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chaneí Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:54:50
User entered empty.	(b) (4) Chanei Henry (b) (4) (b) (4)	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered empty.	System	24 Mar 2021 23:52:22

US3862050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Sep 2020 15:08:02

US3862050

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered '1'	System	25 Sep 2020 15:08:02

US3862050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Sep 2020 15:08:34

US3862050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '01 Oct 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	05 Oct 2020 21:26:15
User entered '25 Sep 2020'	Carrie Kibler (b) (4)	25 Sep 2020 15:08:34

US3862050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	25 Sep 2020 15:08:34

US3862050

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	25 Sep 2020 15:08:34

US3862050

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Sep 2020 15:08:40

US3862050

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'I'	System	25 Sep 2020 15:08:40

US3862050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	28 Sep 2020 14:59:37

US3862050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '05 Oct 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	22 Oct 2020 22:22:29
User entered '01 Oct 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	05 Oct 2020 21:45:47
User entered '28 Sep 2020'	Carrie Kibler (b) (4)	28 Sep 2020 14:59:37

US3862050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	28 Sep 2020 14:59:37

US3862050

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	28 Sep 2020 14:59:37
	(b) (4)	

US3862050

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	28 Sep 2020 14:59:54

US3862050

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'I'	System	28 Sep 2020 14:59:54

US3862050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	22 Oct 2020 23:03:01

US3862050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '12 Oct 2020'	Carrie Kibler (b) (4)	22 Oct 2020 23:03:01

US3862050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	22 Oct 2020 23:03:01

US3862050

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	22 Oct 2020 23:03:01

US3862050

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	22 Oct 2020 23:03:06

US3862050

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'I'	System	22 Oct 2020 23:03:06

US3862050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	26 Oct 2020 19:38:48

US3862050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '26 Oct 2020'	Carrie Kibler (b) (4)	26 Oct 2020 19:38:48

US3862050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[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 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	26 Oct 2020 19:38:48

US3862050

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'VISIT3'	System	26 Oct 2020 19:38:48

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '26 Oct 2020'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '11:36'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered '26 Oct 2020 11:36'	System	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '97.8' F	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Other (Other)'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'temporal'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '64'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'bpm'	System	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '16'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'breaths/min'	System	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '128'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'mmHg'	System	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '82'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'mmHg'	System	26 Oct 2020 19:39:32

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46

US3862050

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46

US3862050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'No (N)'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:36

US3862050

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered empty.	Carrie Kibler (b) (4)	26 Oct 2020 19:39:36

US3862050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 26OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:11:35
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 26OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'PPD status shipped from site. In Transit.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 18:46:38
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 26OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:26:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 19:39:43

US3862050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '26 Oct 2020'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:43
	(b) (4)	

US3862050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered '11:59'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:43

US3862050

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered '26 Oct 2020 11:59'	System	26 Oct 2020 19:39:43

US3862050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:35:52
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	26 Oct 2020 19:39:48

US3862050

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'I'	System	26 Oct 2020 19:39:48

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 64'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Have you been exposed to someone with 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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 20:52:33
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US3862050

Folder: Safety Follow Up Diary (1)

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[Please 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 20:52:33
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
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US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 71'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Have you been exposed to someone with 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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3862050

Folder: Safety Follow Up Diary (1)

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[Please 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 20:52:33
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US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3862050

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

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Generated On: 12 Aug 2021 13:30:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
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US3862050

Folder: Safety Follow Up Diary (1)

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[Please 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 20:52:33
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US3862050

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[Date and time of submission](#)

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US3862050

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered 'Day 78'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
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US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Have you been exposed to someone with 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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 19:07:46

US3862050

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:54:11
Data entry locked.	System	24 Aug 2020 19:07:46
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 19:07:46

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 (050a06987d99b42a)', Time: '2021-03-24T12:50:01', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3ca24079-4e9f-448f-b0fa-9e5aa6626051'	System	24 Mar 2021 17:50:18
User entered 'No (N)'	System	24 Mar 2021 17:50:18

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

Have you been exposed to someone with 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 (050a06987d99b42a)', Time: '2021-03-24T12:50:07', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3ca24079-4e9f-448f-b0fa-9e5aa6626051'	System	24 Mar 2021 17:50:18
User entered 'No (N)'	System	24 Mar 2021 17:50:18

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2021-03-24T12:50:12', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '3ca24079-4e9f-448f-b0fa-9e5aa6626051'	System	24 Mar 2021 17:50:18
User entered '24 Mar 2021 12:50:12'	System	24 Mar 2021 17:50:18

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[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 (050a06987d99b42a)', Time: '2021-04-02T11:17:12', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '0b0ff784-bbdd-4590-8264-d62102884380'	System	02 Apr 2021 16:17:29
User entered 'No (N)'	System	02 Apr 2021 16:17:29

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Have you been exposed to someone with 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 (050a06987d99b42a)', Time: '2021-04-02T11:17:16', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '0b0ff784-bbdd-4590-8264-d62102884380'	System	02 Apr 2021 16:17:29
User entered 'No (N)'	System	02 Apr 2021 16:17:29

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2021-04-02T11:17:19', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '0b0ff784-bbdd-4590-8264-d62102884380'	System	02 Apr 2021 16:17:29
User entered '02 Apr 2021 11:17:19'	System	02 Apr 2021 16:17:29

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:54:11

US3862050

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:30:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:54:11
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:54:11

US3862050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:30:28

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 20:52:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2021-03-02T16:12:18', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '94323e47-3f29-4690-818b-46413e268537'	System	02 Mar 2021 22:12:28
User entered 'No (N)'	System	02 Mar 2021 22:12:28

US3862050

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:30:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:52:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (050a06987d99b42a)', Time: '2021-03-02T16:12:25', User OID: 'PatientReportedOutcome (US3862050)', ODM File OID: '94323e47-3f29-4690-818b-46413e268537'	System	02 Mar 2021 22:12:28
User entered '02 Mar 2021 16:12:25'	System	02 Mar 2021 22:12:28

US3862050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:26:43
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Nov 2020 16:55:48

US3862050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:26:43
User entered '17 Nov 2020'	Carrie Kibler (b) (4)	17 Nov 2020 16:55:48

US3862050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:26:43
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	17 Nov 2020 16:55:48

US3862050

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:26:43
User entered empty.	Carrie Kibler (b) (4)	17 Nov 2020 16:55:48

US3862050

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:26:43
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	17 Nov 2020 16:56:04

US3862050

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:38:46
User entered 'I'	System	17 Nov 2020 16:56:04

US3862050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	23 Dec 2020 16:55:09

US3862050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '23 Dec 2020'	Carrie Kibler (b) (4)	23 Dec 2020 16:55:09

US3862050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	23 Dec 2020 16:55:09

US3862050

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4)	23 Dec 2020 16:55:09

US3862050

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	23 Dec 2020 16:55:25

US3862050

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User entered 'I'	System	23 Dec 2020 16:55:25

US3862050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 17:55:16

US3862050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 17:55:16

US3862050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 17:55:16

US3862050

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 17:55:16

US3862050

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 17:55:35

US3862050

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User entered 'I'	System	20 Jan 2021 17:55:35

US3862050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'No (N)'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:12

US3862050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:12

US3862050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:12

US3862050

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:12

US3862050

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:16

US3862050

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:36:19
User entered '1'	System	25 Feb 2021 22:40:16

US3862050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	20 Apr 2021 18:34:46

US3862050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '02 Apr 2021'	Sandra Francisco (b) (4)	20 Apr 2021 18:34:46

US3862050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4)	20 Apr 2021 18:34:46

US3862050

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 18:34:46

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '02 Apr 2021'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '11:33'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 11:33'	System	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '97.3' F	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Other (Other)'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'temporal'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '70'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '16'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '126'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '84'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 18:35:18

US3862050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:32

US3862050

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '02 Apr 2021'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:32

US3862050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:43

US3862050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '02 Apr 2021'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:43

US3862050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '11:42'	Sandra Francisco (b) (4)	20 Apr 2021 18:35:43

US3862050

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 11:42'	System	20 Apr 2021 18:35:43

US3862050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	19 Apr 2021 16:38:01

US3862050

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:38:01

US3862050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 19:33:34

US3862050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered '19 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 19:33:34

US3862050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Apr 2021 19:33:34

US3862050

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 19:33:34

US3862050

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 13:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 19:33:42

US3862050

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 19:33:42

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:30:28

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:17
User closed query 'Per source, contact occurred on 31Aug20. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:17:09
Query 'Per source, contact occurred on 31Aug20. Please update.' answered with 'Date of contact (Illness Visit) is correct 01 Sep 2020. Date of safety phone call was 31 Aug 2020' (Site from CRA).	Thea Marie Cordero	29 Oct 2020 20:39:35
User opened query 'Per source, contact occurred on 31Aug20. Please update.' (Site from CRA).	(b) (4)	
User entered '1 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 20:36:51
	Carrie Kibler (b) (4)	03 Sep 2020 18:27:23
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:30:28

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:18
User closed query 'Per source, contact occurred at 09:00. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:17:13
Query 'Per source, contact occurred at 09:00. Please update.' answered with 'Time of contact is correct' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:39:58
User opened query 'Per source, contact occurred at 09:00. Please update.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:37:11
User entered '14:25' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Sep 2020 13:56:24
User entered '14:00'	Carrie Kibler (b) (4)	03 Sep 2020 18:27:23

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:30:28

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '1 Sep 2020 14:25'	System	04 Sep 2020 13:56:24
User entered '1 Sep 2020 14:00'	System	03 Sep 2020 18:27:23

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:30:28

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:17:20
User closed query 'Per source, this was a safety call. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:17:15
Query 'Per source, this was a safety call. Please update.' answered with 'Clinic visit as unscheduled is correct' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:40:21
User opened query 'Per source, this was a safety call. Please update.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:42:49
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:27:23

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:30:28

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:27:23
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'Day 1 (Day 1)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 20:33:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 20:33:55
User entered '29 Aug 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 20:24:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0' reason for change: Data Entry Error	Sandra Francisco (b) (4)	22 Mar 2021 23:37:38
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:46:26
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:46:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered '0'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:18
User closed query 'Per CDM Re-query: Site response is noted. If O2 Saturation and Temperature were not recorded. Please consider recording these as "Not Done". for Days 1- 3. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:34:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
Query 'Per CDM Re-query: Site response is noted. If O2 Saturation and Temperature were not recorded. Please consider recording these as "Not Done". for Days 1- 3. ' answered with 'updated EDC to ND' (Site from DM).	Sandra Francisco (b) (4)	22 Mar 2021 23:38:39
DataPoint Un-verified.	Sandra Francisco (b) (4)	22 Mar 2021 23:37:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Mar 2021 23:37:38
User opened query 'Per CDM Re-query: Site response is noted. If O2 Saturation and Temperature were not recorded. Please consider recording these as "Not Done". for Days 1- 3. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:45:07
User closed query 'Per CDM: It appears that O2 Saturation was not recorded Days 1-3. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:45:07
Query 'Per CDM: It appears that O2 Saturation was not recorded Days 1-3. If not collected, please consider recording these as NOT DONE' answered with 'O2 SATURATION ASSESSMENT WERE NOT DONE FROM DAYS 1-3 SINCE DURING THOSE DAYS SUBJECT DID NOT HAVE YET THE PULSE OXIMETER' (Site from DM).	Thea Marie Cordero (b) (4)	24 Feb 2021 23:46:41
User opened query 'Per CDM: It appears that O2 Saturation was not recorded Days 1-3. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:39:50
User closed query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:25:48

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' answered with 'Not done, subject at home, no Pulse oximeter' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:51:06
User opened query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 11:37:07
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered '98'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	22 Mar 2021 23:37:38
User entered empty.	System	15 Sep 2020 20:24:05
User entered '%'	System	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered '102.4' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered '98.6' F	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'Mild (Mild)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'Mild (Mild)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Sep 2020 13:54:06
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:15:26
User entered 'Mild (Mild)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:33:55
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:24:05
User entered 'None (None)'	Carrie Kibler (b) (4)	04 Sep 2020 13:53:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 2 (Day 2)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered '30 Aug 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Sandra Francisco (b) (4)	22 Mar 2021 23:38:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Mar 2021 23:38:48
User closed query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:52:42
Query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' answered with 'Not done, subject at home, no pulse oximeter' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:51:49
User opened query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 11:37:27
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	22 Mar 2021 23:38:48
User entered empty.	System	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered '100.2' F	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:16:26
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:43:45

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 3 (Day 3)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:23
User entered '31 Aug 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:25
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Sandra Francisco (b) (4)	22 Mar 2021 23:41:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Mar 2021 23:41:23
User closed query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:55:56
Query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' answered with 'Not done, subject at home, no pulse oximeter' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:54:10
User opened query 'Please capture ND - Not Done if O2 saturation not collected at this timepoint.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 11:37:39
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:26
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	22 Mar 2021 23:41:23
User entered empty.	System	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per source, subject reported temperature of 99.2F. Please update.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:08:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
Query 'Per source, subject reported temperature of 99.2F. Please update.' answered with 'Late entry' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:54:46
User entered '99.2' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 21:54:36
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:29
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:28
User opened query 'Per source, subject reported temperature of 99.2F. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:17:19
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:17:35
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:45:56

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 4 (Day 4)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	(b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:21:06
User entered '1 Sep 2020'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:21:07
User entered '0'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:21:09
User entered '98'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:21:11
User entered '98.6' F	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:09
User closed query 'Per source, it appears subject reported Mild chills on this date. Please update.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:00:08
Query 'Per source, it appears subject reported Mild chills on this date. Please update.' answered with 'Data is correct, no chills' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:57:05
User opened query 'Per source, it appears subject reported Mild chills on this date. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:19:47
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:12
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:14
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:15
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per source, it appears subject reported Mild fatigue on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:00:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:16
Query 'Per source, it appears subject reported Mild fatigue on this date. Please update' answered with 'Data correct, no fatigue' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:01:23
User opened query 'Per source, it appears subject reported Mild fatigue on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:20:30
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:21
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:29
User closed query 'Per source, it appears subject reported Mild body aches on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:00:28
Query 'Per source, it appears subject reported Mild body aches on this date. Please update' answered with 'Data correct' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:02:39
User opened query 'Per source, it appears subject reported Mild body aches on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:20:20
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:34
User closed query 'Per source, it appears subject reported Mild headaches on this date. Please update' (Site from CRA).		28 Oct 2020 21:00:32
Query 'Per source, it appears subject reported Mild headaches on this date. Please update' answered with 'Data correct, no headache' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:03:34
User opened query 'Per source, it appears subject reported Mild headaches on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:20:45
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:36
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:37
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:39
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:40
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:41
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:43
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:47
User entered 'None (None)'	Thea Marie Cordero	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:00:49
User closed query 'Per source, it appears subject reported Mild sore throat on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:00:46
Query 'Per source, it appears subject reported Mild sore throat on this date. Please update' answered with 'Data correct, no sore throat' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:05:13
User opened query 'Per source, it appears subject reported Mild sore throat on this date. Please update' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:21:02
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:53:37
DataPoint activated with code reason code Data required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:52:20
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:51:03

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 5 (Day 5)' reason for change:	Thea Marie Cordero	15 Sep 2020 20:55:29
Data Entry Error	(b) (4)	
User entered 'Day 4 (Day 4)'	Thea Marie Cordero	15 Sep 2020 20:50:00
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered '2 Sep 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:55:29
User entered '1 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:27:44
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:55:29
User entered '98'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:27:44
User entered empty.	System	15 Sep 2020 20:55:29
User entered '%'	System	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered '98.3' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:27:44
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:55:29
User entered '98.6' F	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 20:55:29
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:02:07
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:50:00

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 6 (Day 6)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '3 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:28:34
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:28:34
User entered empty.	System	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Sep 2020 21:28:43
User entered '98.6' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:28:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Sep 2020 21:28:34
User entered '98.6' (non-conformant).	Thea Marie Cordero (b) (4)	15 Sep 2020 21:28:34
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:56:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 7 (Day 7)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered '4 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:06
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:29:06
User entered empty.	System	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered '99' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:06
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:25:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 20:59:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 8 (Day 8)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '5 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:32
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:29:32
User entered empty.	System	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '97.9' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:32
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:00:47

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 9 (Day 9)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '6 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:58
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:29:58
User entered empty.	System	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98.4' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:29:58
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:01:52

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 10 (Day 10)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '7 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:30:19
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:30:19
User entered empty.	System	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98.5' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:30:19
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:03:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 11 (Day 11)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '8 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:30:47
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:30:47
User entered empty.	System	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98.4' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:30:47
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:04:41

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 12 (Day 12)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '9 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:32:51
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:32:51
User entered empty.	System	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98.3' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:32:51
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:05:51

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 13 (Day 13)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '10 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:33:13
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:33:13
User entered empty.	System	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98.1' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:33:13
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'Mild (Mild)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:06:54

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 14 (Day 14)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '11 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:33:38
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:33:38
User entered empty.	System	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '97.9' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:33:38
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:07:56

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 15 (Day 15)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '12 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:08
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:34:08
User entered empty.	System	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '97.9' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:08
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:08:37

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 16 (Day 16)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '13 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:40
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:34:40
User entered empty.	System	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '98' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:40
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:09:28

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Day 17 (Day 17)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 01OCT2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:06:57
Query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 01OCT2020. Please reconcile' answered with 'Dates correct. Covid positive, no Day 28 recorded.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:14:59
User opened query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 01OCT2020. Please reconcile' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:12:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '14 Sep 2020'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '0'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '99' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:53
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered '%'	System	15 Sep 2020 21:34:53
User entered empty.	System	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered '97.9' F reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Sep 2020 21:34:53
User entered empty.	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:30:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:07:53
User entered 'None (None)'	Thea Marie Cordero (b) (4)	15 Sep 2020 21:10:13

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:31
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:34
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:36
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		03 Sep 2020 20:18:55
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Placed into Adverse Events' (Site from System).	Carrie Kibler (b) (4)	03 Sep 2020 18:28:45
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Sep 2020 18:28:07
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:38
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:13:41
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:30:33
User closed query 'Please verify and correct. This field should be "NO" while the following two fields should be blank based on the question asked.' (Site from CRA).		30 Oct 2020 02:12:55
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 20:32:04
Query 'Please verify and correct. This field should be "NO" while the following two fields should be blank based on the question asked.' answered with 'UPDATED' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:31:46
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 20:31:36
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:31:36
User opened query 'Please verify and correct. This field should be "NO" while the following two fields should be blank based on the question asked.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:41:25
User closed query 'Per lab reports, subject was tested at Central Lab on 01Sep20 during the Illness Visit. Please update to No, as Central Lab results should be used for study purposes.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:41:25
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	26 Oct 2020 22:09:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:09:17

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Query 'Per lab reports, subject was tested at Central Lab on 01Sep20 during the Illness Visit. Please update to No, as Central Lab results should be used for study purposes.' answered with 'Updated' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:07:32
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	26 Oct 2020 22:07:20
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:07:20
User opened query 'Per lab reports, subject was tested at Central Lab on 01Sep20 during the Illness Visit. Please update to No, as Central Lab results should be used for study purposes.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 18:37:16
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:28:07

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:30:35
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:32:04
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 22:09:36
User entered 'Central lab' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:09:36
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 22:09:17
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:07:20
User entered 'Walgreens'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:30:38
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:32:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:09:43
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:08:12
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:28:07

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:30:28

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User entered 'I'	System	03 Sep 2020 18:28:07

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:17:30
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:38
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 21:36:36
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:40:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 23:40:02
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	24 Feb 2021 23:40:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 23:39:42
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:39:42
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:39:42
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:32
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:30
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:28
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:22:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	24 Feb 2021 23:41:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 20:12:26
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:25
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:24
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:22
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:21
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:20
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:18
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:17
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

US3862050

Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:16
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:14
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:10
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:12
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 18:30:29
	(b) (4)	

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:08
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:03
DataPoint Verified.		15 Oct 2020 20:09:35
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:05
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:30:28

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:24:39
DataPoint Un-verified.		15 Oct 2020 20:12:06
DataPoint Verified.		15 Oct 2020 20:09:35
User entered empty.	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:30:29

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Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:30:28

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:33:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Please consider updating to 'No,' as per CRF completion guidelines, should only be 'Yes' should subject experience sx again. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:49:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:49:31
Query 'Please consider updating to 'No,' as per CRF completion guidelines, should only be 'Yes' should subject experience sx again. ' answered with 'updated' (Site from CRA).	Shetel Anassi (b) (4)	10 Nov 2020 16:58:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 16:58:22
User opened query 'Please consider updating to 'No,' as per CRF completion guidelines, should only be 'Yes' should subject experience sx again. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:05:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 16:01:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:01:24
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 13:54:12

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 3 (Day 3)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:36

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:14:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:36
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:25:54
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose. ' answered with 'Per monitor instruction, please disregard this query. Thank you. ' (Site from DM).	Sandra Francisco (b) (4)	25 Feb 2021 19:24:22
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:49:08
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however please provide the tracking details of the same in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 10:02:28
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however please provide the tracking details of the same in the response. Thank you. ' answered with 'ACCESSION NUMBER: 1F60B4L' (Site from DM).	Thea Marie Cordero (b) (4)	22 Dec 2020 19:30:49
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, however please provide the tracking details of the same in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:37:46
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020, 05SEP2020, 07SEP2020 and 14SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:37:46

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020, 05SEP2020, 07SEP2020 and 14SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'WE HAVE RECEIVED THE RESULTS OF THE FOLLOWING SALIVA SAMPLES ON 26 OCT 2020: 1. 26 OCT 2020 FOR THE SAMPLES BELOW: DAY 3/03 SEP 2020, DAY 5/05 SEP 2020, DAY 07/07 SEP 2020, DAY 9/09SEP 2020, DAY 14 /14 SEP 2020 AND DAY 21/21 SEP 2020 THEREFORE THE SAMPLES WERE SHIPPED, ANALYZED AND REPORTED ' (Site from DM).	Thea Marie Cordero (b) (4)	07 Dec 2020 20:52:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03SEP2020, 05SEP2020, 07SEP2020 and 14SEP2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:24:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:15:26
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
User entered '03 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 21:14:55
User entered '3 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:36
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 5 (Day 5)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:40:12
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
User entered '05 Sep 2020' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:01
User entered '5 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 7 (Day 7)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:14
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:40:15
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
User entered '07 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
	(b) (4), (b) (6)	28 Oct 2020 21:15:14
User entered '7 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 9 (Day 9)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:38
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:40:18
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
User entered '09 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:19:17
	(b) (4), (b) (6)	28 Oct 2020 21:15:38
User entered '9 Sep 2020'	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 14 (Day 14)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:54
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:42:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:42:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Chanei Henry (b) (4)	30 Sep 2020 22:42:02
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:58:55
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 14SEP2020 for Day 14 is recorded in EDC , however same is reported with 21SEP2020 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:33:40
Query 'Per GCL Lab Recon: Saliva: Sample dated 14SEP2020 for Day 14 is recorded in EDC , however same is reported with 21SEP2020 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with '14 SEPT is correct. Please note lab is not onsite and dates will differ, from when the received sample. ' (Site from DM).	Shetel Anassi (b) (4)	18 Nov 2020 21:31:11
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 14SEP2020 for Day 14 is recorded in EDC , however same is reported with 21SEP2020 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:17:58
Query 'Per GCL Lab Recon: Saliva: Sample dated 14SEP2020 for Day 14 is recorded in EDC central lab, however same is reported with 21SEP2020 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:17:44
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 14SEP2020 for Day 14 is recorded in EDC central lab, however same is reported with 21SEP2020 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:07:45
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:15:54
User entered '14 Sep 2020' reason for change: Data Entry Error	Chanei Henry (b) (4)	30 Sep 2020 22:42:02
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 21Sep2020 is reported under Illness Visit Day 21 in EDC, however same is reported for Day 14 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:22:25
Query 'Per GCL Lab Recon: Saliva: Sample dated 21Sep2020 is reported under Illness Visit Day 21 in EDC, however same is reported for Day 14 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' answered with 'Source documentation says this is the correct date. ' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	23 Mar 2021 00:18:48
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 21Sep2020 is reported under Illness Visit Day 21 in EDC, however same is reported for Day 14 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:44:16
Query 'Per GCL Lab Recon: Saliva: Sample dated 21Sep2020 is reported under Illness Visit Day 21 in EDC, however same is reported for Day 14 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:43:02
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 21Sep2020 is reported under Illness Visit Day 21 in EDC, however same is reported for Day 14 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:42:04
User accepted default value 'Day 21 (Day 21)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:31:51
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:42:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:42:21
User entered 'Yes (Y)' reason for change: New Information	Chanei Henry (b) (4)	30 Sep 2020 22:42:21
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:58:55
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

US3862050

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:31:53
User entered '21 Sep 2020' reason for change: New Information	Chanei Henry (b) (4)	30 Sep 2020 22:42:21
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

US3862050

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User accepted default value 'Day 28 (Day 28)'	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

US3862050

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:30:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:26:26
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:42:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:42:43
User entered 'Yes (Y)' reason for change: New Information	Chanei Henry (b) (4)	30 Sep 2020 22:42:43
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 22:58:55
User entered empty.	Carrie Kibler (b) (4)	14 Sep 2020 22:58:55

US3862050

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded as Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:35:49
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded as Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' answered with '01 OCT 2020 Is correct.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 21:32:51
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01OCT2020 is recorded as Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva visit in PPD Central lab. Please confirm the correct Visit and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:09:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:40:25
DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 14:19:17
User entered '01 Oct 2020' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 14:19:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:26:26
User entered '1 Oct 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	01 Oct 2020 18:52:03
User entered '28 Sep 2020' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:42:43
User entered empty.	Carrie Kibler (b) (4) (b) (4)	14 Sep 2020 22:58:55

US3862050

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:23:45
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 13:55:37
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:06:41
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:16:44
User entered '01 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:16:44
	(b) (4), (b) (6)	28 Oct 2020 20:23:45
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	04 Sep 2020 13:55:37
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:23:45
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	04 Sep 2020 13:55:37

US3862050

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:25
User entered 'SICKD1'	System	04 Sep 2020 13:55:37

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:03:37
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:06:47
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:17:09
User entered '01 Sep 2020' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	10 Nov 2020 14:17:09
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:03:39
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:05:50
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 20:05:50
User entered '1 Sep 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Sep 2020 20:05:50
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:05:36
User entered '4 Sep 2020'	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:03:40
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 20:05:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	04 Sep 2020 20:05:50
User entered '14:25' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Sep 2020 20:05:50
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 20:05:36
User entered empty.	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User entered '01 Sep 2020 14:25'	System	10 Nov 2020 14:17:09
User entered '1 Sep 2020 14:25'	System	04 Sep 2020 20:05:50
User entered empty.	System	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:28:33
User closed query 'No height measurements are recorded in the Illness Visit source documents. Please review and confirm.' (Site from CRA).		28 Oct 2020 20:28:32
Query 'No height measurements are recorded in the Illness Visit source documents. Please review and confirm.' answered with 'Late entry' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:46:47
User opened query 'No height measurements are recorded in the Illness Visit source documents. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:03:35
User entered '73.7' in	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
DataPoint set to visible.	(b) (4) System	04 Sep 2020 13:55:37

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:28:37
User closed query 'No weight measurements are recorded in the Illness Visit source documents. Please review and confirm.' (Site from CRA).		28 Oct 2020 20:28:36
Query 'No weight measurements are recorded in the Illness Visit source documents. Please review and confirm.' answered with 'Late entry' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:48:35
User opened query 'No weight measurements are recorded in the Illness Visit source documents. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:03:28
User entered '216.6' lb	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
DataPoint set to visible.	(b) (4) System	04 Sep 2020 13:55:37

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:05:29
User entered '98.6' F	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:28:50
User closed query 'Route is not documented in source. Please review and confirm.' (Site from CRA).		28 Oct 2020 20:28:46
Query 'Route is not documented in source. Please review and confirm.' answered with 'Late entry' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 21:49:03
User entered 'Other (Other)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 21:48:21
User opened query 'Route is not documented in source. Please review and confirm.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:05:51
User entered 'Oral (Oral)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Sep 2020 20:05:58
User entered 'Other (Other)'	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:28:51
User entered 'Temporal' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 21:48:21
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	04 Sep 2020 20:05:58
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	04 Sep 2020 20:05:36
User entered empty.	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:05:55
User entered '71'	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User entered 'bpm'	System	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User closed query 'Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:26:32
Query 'Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NOT CLINICALLY SIGNIFICANT' (Site from DM).	Thea Marie Cordero (b) (4)	24 Nov 2020 22:31:03
User opened query 'Per CDM: Respiratory rate >16 and ≤20 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:48:35
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:05:58
User entered '18'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User entered 'breaths/min'	System	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User closed query 'Per CDM: Systolic Blood Pressure >140 and ≤150 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:26:30
Query 'Per CDM: Systolic Blood Pressure >140 and ≤150 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'NOT CLINICALLY SIGNIFICANT' (Site from DM).	Thea Marie Cordero (b) (4)	24 Nov 2020 22:30:33
User opened query 'Per CDM: Systolic Blood Pressure >140 and ≤150 per CCG v2.0 considered grade 1. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:49:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:06:03
User entered '144'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User entered 'mmHg'	System	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:06:04
User entered '89'	Carrie Kibler (b) (4)	04 Sep 2020 20:05:36
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33
User entered 'mmHg'	System	04 Sep 2020 20:05:36

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33

US3862050

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:33

US3862050

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:06:25
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 14:01:35

US3862050

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:07:02
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:17:32
User entered '01 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:17:32
	(b) (4), (b) (6)	15 Oct 2020 20:06:25
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	04 Sep 2020 14:01:35
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:30:28

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:07:58
DataPoint Un-verified.		10 Nov 2020 16:07:55
DataPoint Verified.		15 Oct 2020 20:08:10
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	08 Sep 2020 22:26:52
	(b) (4)	

US3862050

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:07:57
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:17:39
User entered '01 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:17:39
	(b) (4), (b) (6)	15 Oct 2020 20:08:10
User entered '1 Sep 2020'	Carrie Kibler (b) (4)	08 Sep 2020 22:26:52
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:38:16
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	01 Oct 2020 18:53:47
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:09:39
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:10
User entered '01 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:10
	(b) (4), (b) (6)	15 Oct 2020 20:38:16
User entered '1 Oct 2020'	Carrie Kibler (b) (4)	01 Oct 2020 18:53:47
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:38:16
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	01 Oct 2020 18:53:47
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:09
User entered 'SICKD28'	System	01 Oct 2020 18:53:47

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:27:03
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:14:25
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:34
User entered '01 Oct 2020' reason for change: Per Query Resolution	(b) (4)	10 Nov 2020 14:18:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:27:05
User entered '1 Oct 2020'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 16:13:13
User closed query 'Per source, time was 11:58. Please update.' (Site from CRA).		07 Nov 2020 16:13:11
Query 'Per source, time was 11:58. Please update.' answered with 'data corrected' (Site from CRA).	Trent Davis (b) (4)	04 Nov 2020 19:02:37
User entered '11:58' reason for change: Data Entry Error	Trent Davis (b) (4)	04 Nov 2020 19:02:31
User opened query 'Per source, time was 11:58. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 20:40:16
User entered '12:42'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User entered '01 Oct 2020 11:58'	System	10 Nov 2020 14:18:34
User entered '1 Oct 2020 11:58'	System	04 Nov 2020 19:02:31
User entered '1 Oct 2020 12:42'	System	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:27:13
User entered '98' F	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 16:13:24
User closed query 'Per source, route was temporal. Please update.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:13:23
Query 'Per source, route was temporal. Please update.' answered with 'data corrected' (Site from CRA).	Trent Davis (b) (4)	04 Nov 2020 19:02:44
User entered 'Other (Other)' reason for change: Data Entry Error	Trent Davis (b) (4)	04 Nov 2020 19:02:31
User opened query 'Per source, route was temporal. Please update.' (Site from CRA).	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Oct 2020 21:27:29
	(b) (4), (b) (6)	
	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 16:13:26
User entered 'temporal' reason for change: Data Entry Error	Trent Davis (b) (4)	04 Nov 2020 19:02:31
User entered empty.	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:27:38
User entered '64'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User entered 'bpm'	System	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:27:43
User entered '16'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User entered 'breaths/min'	System	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:29:26
User entered '129'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User entered 'mmHg'	System	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:29:27
User entered '82'	Carrie Kibler (b) (4)	01 Oct 2020 18:57:46
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17
User entered 'mmHg'	System	01 Oct 2020 18:57:46

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:30:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:17

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 20:40:31
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	01 Oct 2020 18:58:06
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:14:52
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:40
User entered '01 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:40
	(b) (4), (b) (6)	15 Oct 2020 20:40:31
User entered '1 Oct 2020'	Carrie Kibler (b) (4)	01 Oct 2020 18:58:06
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:30:28

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:35:58
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	01 Oct 2020 18:58:13
	(b) (4)	

US3862050

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:30:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:04:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:15:05
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:48
User entered '01 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Sandra Francisco (b) (4)	10 Nov 2020 14:18:48
	(b) (4), (b) (6)	28 Oct 2020 21:35:58
User entered '1 Oct 2020'	Carrie Kibler (b) (4)	01 Oct 2020 18:58:13
	(b) (4)	

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:03

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:03

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:03

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 20:27:03

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:31:52

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
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 06:31:52

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '1'	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:30:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'I'	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered empty.	System	25 Feb 2021 22:40:55
DataPoint set to visible.	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered empty.	System	25 Feb 2021 22:40:55
DataPoint set to visible.	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55
	(b) (4)	

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '14:08'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '25 Feb 2021 14:08'	System	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '98.2' F	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Other (Other)'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'temporal'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '72'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'bpm'	System	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '15'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'breaths/min'	System	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '138'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'mmHg'	System	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '77'	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'mmHg'	System	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	25 Feb 2021 22:40:55

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:30:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered empty.	System	25 Feb 2021 22:40:55
DataPoint set to visible.	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29
	(b) (4)	

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '16:08'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '25 Feb 2021 16:08'	System	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '97.9' F	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Other (Other)'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'temporal'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '71'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'bpm'	System	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '16'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'breaths/min'	System	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '145'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'mmHg'	System	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '85'	Carrie Kibler (b) (4)	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'mmHg'	System	25 Feb 2021 22:41:29

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:26

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:26

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Carrie Kibler (b) (4) (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'mRNA-1273'	System	25 Feb 2021 22:42:14
DataPoint set to visible.	System	25 Feb 2021 20:27:17

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '15:38'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '25 Feb 2021 15:38'	System	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'ONCE'	System	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 22:42:14

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:58:09

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 20:58:09

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '14:17'	Carrie Kibler (b) (4)	25 Feb 2021 20:58:09

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:30:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '25 Feb 2021 14:17'	System	25 Feb 2021 20:58:09

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:30:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:28

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:30:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '25 Feb 2021'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:28
	(b) (4)	

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:30:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '14:15'	Carrie Kibler (b) (4)	25 Feb 2021 22:42:28

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:30:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered '25 Feb 2021 14:15'	System	25 Feb 2021 22:42:28

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Feb 2021 20:27:34

US3862050

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:05
User entered 'I'	System	25 Feb 2021 20:27:34

US3862050

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	05 Mar 2021 14:59:16

US3862050

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered '5 Mar 2021'	Thea Marie Cordero (b) (4)	05 Mar 2021 14:59:16

US3862050

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero (b) (4)	05 Mar 2021 14:59:16

US3862050

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered empty.	Thea Marie Cordero (b) (4)	05 Mar 2021 14:59:16

US3862050

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	05 Mar 2021 14:59:26

US3862050

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User entered 'I'	System	05 Mar 2021 14:59:26

US3862050

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:52
User entered 'I'	System	05 Mar 2021 14:59:26
DataPoint set to visible.	System	05 Mar 2021 14:59:26

US3862050

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:29

US3862050

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '02 Apr 2021'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:29
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:29
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:30:28

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	02 Apr 2021 17:39:29

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '02 Apr 2021'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '11:33'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 11:33'	System	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '97.3' F	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Other (Other)'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'temporal'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '70'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '16'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '126'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '84'	Carrie Kibler (b) (4)	02 Apr 2021 17:41:59
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 17:41:59

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '02 Apr 2021'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '13:04'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 13:04'	System	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '97.8' F	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Other (Other)'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'temporal'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '62'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '16'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '148'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '79'	Carrie Kibler (b) (4)	02 Apr 2021 18:15:53
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:30:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:15:53

US3862050

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:50

US3862050

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:30:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '02 Apr 2021'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:50
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered empty.	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered empty.	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	02 Apr 2021 17:39:40
DataPoint set to visible.	System	05 Mar 2021 14:59:26

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '02 Apr 2021'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered '12:34'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 12:34'	System	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:40
	(b) (4)	

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:30:28

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Apr 2021 17:39:40

US3862050

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:33:01
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	02 Apr 2021 17:39:43

US3862050

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 17:39:43

US3862050

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:19:15

US3862050

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:41:38
User entered '12 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 14:19:15

US3862050

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:41:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Apr 2021 14:19:15

US3862050

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:30:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:41:38
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 14:19:15

US3862050

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:41:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:19:21

US3862050

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:30:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 14:19:21

US3862050

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:30:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:43
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:12:51
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 01SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 02:54:18
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 01SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	Thea Marie Cordero (b) (4)	25 Feb 2021 00:17:23
' answered with 'AE CREATED' (Site from DM). User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 01SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 10:52:32
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:57:54
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:14:35

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4)	28 Oct 2020 21:37:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:00:40
User entered	System	10 Sep 2020 15:57:55
'USA-US121-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 15:57:55

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:11:49
User closed query 'Please change term back to Symptomatic COVID-19, as DM query was issued incorrectly to change the term previously.' (Site from CRA).		24 Nov 2020 23:11:47
Query 'Please change term back to Symptomatic COVID-19, as DM query was issued incorrectly to change the term previously.' answered with 'update: EDC and source documents now say symptomatic covid-19' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 22:07:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:03:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:03:59
Data point term sent to Coder	System	24 Nov 2020 22:03:12
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 22:02:25
User entered 'symptomatic COVID-19' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 22:02:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:27
User opened query 'Please change term back to Symptomatic COVID-19, as DM query was issued incorrectly to change the term previously.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:14:22
Data point term sent to Coder	System	23 Nov 2020 16:03:40
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 16:03:39

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Adverse event](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'UPDATED' (Site from System).	Shetel Anassi (b) (4)	23 Nov 2020 16:03:39
Data point term sent to Coder DataPoint Un-verified.	System	23 Nov 2020 16:03:39
	Shetel Anassi (b) (4)	23 Nov 2020 16:03:31
Coding entries removed.	Shetel Anassi (b) (4)	23 Nov 2020 16:03:31
	(b) (4)	
User entered 'COVID-19' reason for change: New Information	Shetel Anassi (b) (4)	23 Nov 2020 16:03:31
	(b) (4)	
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:23:54
	(b) (4)	
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:10:51
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'confirmed' (Site from DM).	Shetel Anassi (b) (4)	18 Nov 2020 20:42:12
	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:24:30
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:37:51
	(b) (4), (b) (6)	
User closed query 'Please update term to Symptomatic COVID-19 to accurately report the case.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:37:46
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:13:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:13:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Please update term to Symptomatic COVID-19 to accurately report the case.' answered with 'Updated' (Site from CRA).	Thea Marie Cordero	26 Oct 2020 22:12:31
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	26 Oct 2020 22:12:14
	Thea Marie Cordero	26 Oct 2020 22:12:02
	(b) (4)	
User entered 'Symptomatic COVID-19' reason for change: New Information	Thea Marie Cordero	26 Oct 2020 22:12:02
	(b) (4)	
User opened query 'Please update term to Symptomatic COVID-19 to accurately report the case.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 19:51:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 00:33:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 00:33:42
	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 00:32:35
Coding entries removed.	Coni Cheesman (b) (4)	02 Sep 2020 00:32:14
User entered 'COVID-19' reason for change: New Information	Coni Cheesman (b) (4)	02 Sep 2020 00:32:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Pyrexia - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 06:02:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 06:02:43
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 23:28:55
User entered 'Febrile Illness'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:51:25
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 08:06:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:38:07
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'Updated' (Site from DM).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:13:48
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:13:37
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:03:19
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:33:08
User entered 'Yes (Y)' reason for change: New Information	Coni Cheesman (b) (4)	09 Sep 2020 14:43:33
User entered 'No (N)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:32
User entered '29 Aug 2020'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 21:38:51
User closed query 'Per source, start time was 23:25. Please update' (Site from CRA).		28 Oct 2020 21:38:49
Query 'Per source, start time was 23:25. Please update' answered with 'Removed start time' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:16:44
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Oct 2020 22:16:23
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:16:23
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Oct 2020 22:14:11
User entered '23:25' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:14:11
User opened query 'Per source, start time was 23:25. Please update' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 19:52:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 00:30:24
User entered empty; reason for change Data Entry Error	Coni Cheesman (b) (4)	02 Sep 2020 00:30:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 23:28:38
User entered '23:25'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 22:16:23
User entered '29 Aug 2020 23:25'	System	26 Oct 2020 22:14:11
User entered empty.	System	02 Sep 2020 00:30:24
User entered '29 Aug 2020 23:25'	System	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 21:38:58
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:22:53
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:16:55
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved). Please leave query open until information is available.' (Site from Safety).		27 Oct 2020 15:45:07
Query 'PV Query: Please provide the event end date (when symptoms have resolved). Please leave query open until information is available.' answered with 'Updated' (Site from Safety).	Thea Marie Cordero	26 Oct 2020 22:23:23
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Oct 2020 22:23:14
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	26 Oct 2020 22:23:14
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	26 Oct 2020 22:22:53
User entered '11 Sep 2020' reason for change: Data Entry Error	Thea Marie Cordero	26 Oct 2020 22:22:53
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:14:17
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:14:17
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'Ongoing' (Site from Safety).	Chanei Henry	16 Sep 2020 23:38:52
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 16:05:18
User entered empty.	Coni Cheesman	31 Aug 2020 23:28:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 21:39:50
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:52:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:00
User entered 'No (N)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:03
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 19:53:04
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

US3862050

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:06
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:07
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:09
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:10
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:12
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:14
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:15
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:17
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:20
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 00:30:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 00:30:50
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Coni Cheesman (b) (4) (b) (4)	02 Sep 2020 00:30:50
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:28:38
User entered empty.	Coni Cheesman (b) (4) (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:53:23
User entered 'Not Related (NOT RELATED)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User closed query 'Per CDM: Investigational Product Withdrawn is noted. According to CCGs v2 (23Oct2020) pgs. 42-43, the Dosing Discontinuation eCRF located in the End of Study folder should be recorded. Please note the date of dosing discontinuation as the date of last dosing exposure. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:13:06
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 08:13:03
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).	Shetel Anassi (b) (4)	18 Nov 2020 20:51:41
Query 'Per CDM: Investigational Product Withdrawn is noted. According to CCGs v2 (23Oct2020) pgs. 42-43, the Dosing Discontinuation eCRF located in the End of Study folder should be recorded. Please note the date of dosing discontinuation as the date of last dosing exposure. Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	18 Nov 2020 20:50:02
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 Nov 2020 17:24:55
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 16:14:02
User closed query 'Please correct action on the page to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:13:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Investigational Product Withdrawn is noted. According to CCGs v2 (23Oct2020) pgs. 42-43, the Dosing Discontinuation eCRF located in the End of Study folder should be recorded. Please note the date of dosing discontinuation as the date of last dosing exposure. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 19:29:31
Query 'Please correct action on the page to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' answered with 'UPDATED' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 22:22:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 22:22:47
User closed query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:07:17
User opened query 'Please correct action on the page to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:42:01
User closed query 'Please correct action to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:42:01
Query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' answered with 'Treatment discontinued' (Site from DM).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:29:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:28:52
Query 'Please correct action to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' answered with 'Treatment discontinued' (Site from CRA).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:26:12

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Please correct action to Treatment Discontinued, as subject was no longer eligible to receive Dose 2.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 19:54:06
User opened query 'Per MM, please confirm if action taken with IP is correct, per protocol sec 7.2, if the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses of vaccine but will be encouraged to continue study participation for safety through 24 months following last dose' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:58:17
User entered 'None (NONE)'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:54:19
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 19:54:20
User closed query 'Per CDM: Concomitant Medication is selected, however, there is no data recorded on Concomitant Medication form. Per Protocol, all clinical findings will be recorded in the eCRF. All confirmed cases of COVID-19 will be captured as MAAEs, along with relevant concomitant medications and details about severity, seriousness, and outcome. Please verify and update all applicable forms as appropriate. Thank you.' (Site from DM).		11 Sep 2020 15:44:59
Query 'Per CDM: Concomitant Medication is selected, however, there is no data recorded on Concomitant Medication form. Per Protocol, all clinical findings will be recorded in the eCRF. All confirmed cases of COVID-19 will be captured as MAAEs, along with relevant concomitant medications and details about severity, seriousness, and outcome. Please verify and update all applicable forms as appropriate. Thank you.'	Carrie Kibler (b) (4)	04 Sep 2020 14:00:24
answered with 'Confirmed entered.' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Concomitant Medication is selected, however, there is no data recorded on Concomitant Medication form. Per Protocol, all clinical findings will be recorded in the eCRF. All confirmed cases of COVID-19 will be captured as MAAEs, along with relevant concomitant medications and details about severity, seriousness, and outcome. Please verify and update all applicable forms as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 22:58:46
User entered 'I'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:54:23
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:17:03
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).		27 Oct 2020 15:43:52
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Recovered' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Oct 2020 22:29:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	26 Oct 2020 22:23:14
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 16:05:32
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 22:51:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 22:51:39
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:51:39
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:28:38
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:54:36
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User closed query 'Per DM CLR: Narrative indicates that the subject has Biofire RPS testing for other viral pathogens. However, there is no corresponding Concomitant Procedure record that match this information. Please review and update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 08:37:36
User closed query 'PV Query: Please confirm the results for the Biofire RPS.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:59:36
Query 'Per DM CLR: Narrative indicates that the subject has Biofire RPS testing for other viral pathogens. However, there is no corresponding Concomitant Procedure record that match this information. Please review and update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:47:58
Query 'PV Query: Please confirm the results for the Biofire RPS.' answered with 'Per notes results tested postive' (Site from Safety).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:45:51
User opened query 'Per DM CLR: Narrative indicates that the subject has Biofire RPS testing for other viral pathogens. However, there is no corresponding Concomitant Procedure record that match this information. Please review and update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:17:48
User opened query 'PV Query: Please confirm the results for the Biofire RPS.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:31:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:05
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 15:44:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: On 01 Sep 2020, SARS-CoV-2 RT-PCR nasopharyngeal swab was performed. Please provide date results returned positive.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 15:44:19
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 15:43:32
User closed query 'PV Query: Please provide baseline (Day 1) SARS-CoV-2 RT-PCR results and date results were received.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 15:43:13
Query 'PV Query: On 01 Sep 2020, SARS-CoV-2 RT-PCR nasopharyngeal swab was performed. Please provide date results returned positive.'	Thea Marie Cordero	26 Oct 2020 22:42:32
answered with 'SARS-CoV-2 RT-PCR nasopharyngeal swab (01 Sep 2020) Received result: 09 Sep 2020' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide baseline (Day 1) SARS-CoV-2 RT-PCR results and date results were received.'	Thea Marie Cordero	26 Oct 2020 22:40:26
answered with 'Baseline SARS CoV-2 RT PCR (24 Aug 2020),Result- Not detected, Result received: 08 Sep 2020' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.'	Thea Marie Cordero	26 Oct 2020 22:35:16
answered with 'Subject took Nyquil liquid and Tylenol liquid. Updated in concomitant medication list' (Site from Safety).	(b) (4)	
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.'	Thea Marie Cordero	26 Oct 2020 22:30:35
answered with 'Exposed to work partner who tested positive for COVID 19 28 Aug 2020' (Site from Safety).	(b) (4)	
User opened query 'PV Query: On 01 Sep 2020, SARS-CoV-2 RT-PCR nasopharyngeal swab was performed. Please provide date results returned positive.'	(b) (4), (b) (6)	15 Sep 2020 16:06:44
(Site from Safety).		
User opened query 'PV Query: Please provide baseline (Day 1) SARS-CoV-2 RT-PCR results and date results were received.'	(b) (4), (b) (6)	15 Sep 2020 16:06:23
(Site from Safety).		

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 16:06:05
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Sep 2020 16:05:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported the following: 1. Rode with his partner 26 Aug 2020 2. Subject's partner tested positive for COVID-19 on 28-AUG-2020 3. 29-AUG-2020 (Day 6): Temperature 102.4°F with "mild" chills, fatigue, sore throat. Took Nyquil 2-3 teaspoons and Tylenol liquid 2-3 teaspoons 4. 30-AUG-2020 (Day 7): Temperature 100.2°F with "mild" chills, fatigue, headache, body aches Took Tylenol 3 teaspoons 5. 31-AUG-2020 (Day 8): Morning temperature 99.2°F Afternoon temperature 98.5°F Still with "mild" body aches, rest of symptoms subsided 01 Sep 2020: Morning temperature: 97.4°F, still with "mild" body aches. Denies any other symptoms 8:00 am Had rapid testing at Walgreens 10:30 am Received phone call—Tested positive for SARS CoV-2 Started quarantine today Illness Visit: 14:25: Vital Signs: BP 144/89, P 71, R 18, T 98.6°F, O2 saturation 98% (Room air) PE: Not acutely ill, Lungs: Bilateral- clear on auscultation ENT: no significant findings Lab work done: NP swab collections done (PCR for SARS-CoV-2) and Biofire RPS for other viruses Subject was informed, given explanations and instructions on the following: 1) Telemedicine or phone call daily x 14days or until symptoms resolve, subject prefers phone calls 2) Daily checking/monitoring of oral temperature and O2 saturation level 3) Home saliva collections: Day 3-Day 21 4) Advised to follow up with PCP, seek immediate medical help for severe respiratory symptoms, shortness of breath, rapid heart rate, O2 saturation <u><</u> 93%, severe chills, Temperature <u>></u>100.4. 5) Subject verbalized understanding and agreement of plan.' reason for change: New Information User entered empty.	Coni Cheesman (b) (4)	10 Sep 2020 18:12:39
	Coni Cheesman (b) (4)	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 23:28:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:30:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 23:28:38

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 00:19:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 00:19:12
Data point term sent to Coder	System	25 Feb 2021 00:18:43
User entered 'FATIGUE'	Thea Marie Cordero	25 Feb 2021 00:18:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'No (N)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'No (N)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 29Aug2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:13:34
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 29Aug2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'solicited adverse events start dates would start after the post reactogenicity period ends. no changes needed. ' (Site from DM).	Sandra Francisco (b) (4)	23 Mar 2021 00:22:41
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 29Aug2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:09:30
User entered '31 Aug 2020'	Thea Marie Cordero (b) (4)	25 Feb 2021 00:18:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User entered empty.	System	25 Feb 2021 00:18:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'No (N)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '01 Sep 2020'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User entered empty.	System	25 Feb 2021 00:18:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'No (N)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Related (RELATED)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Not Related (NOT RELATED)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'I'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered '0'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:21:40
User entered empty.	(b) (4)	25 Feb 2021 00:18:39
	Thea Marie Cordero	
	(b) (4)	

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User entered '0'	System	25 Feb 2021 00:18:39

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49
User entered '0'	System	25 Feb 2021 00:18:39

US3862050

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:30:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:40:49

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:30:28

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Conmed referring to the timeframe of Diary dose 1, day 7 correlate to items taken for the now updated AE#01. Please review conmed entry and provide additional instructions if query is not resolved. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:27:24
	Sandra Francisco (b) (4)	24 Nov 2020 22:14:07
	(b) (4)	
User opened query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:21:57
	(b) (4), (b) (6)	28 Oct 2020 21:43:16
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:34:30
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 19:36:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 19:36:47
Data point term sent to Coder	System	24 Aug 2020 19:36:13
User entered 'Pepcid'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'GERD'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '20'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'mg (mg)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'as needed (PRN)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Oral (ORAL)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'UN Jan 2020'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Yes (Y)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered empty.	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'No (N)'	Chanei Henry (b) (4)	24 Aug 2020 19:36:02
	(b) (4)	

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:36:02

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:36:02

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 19:36:02

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 20:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 20:19:55
Data point term sent to Coder	System	29 Oct 2020 22:18:36
Data point term sent to Coder	System	27 Oct 2020 17:10:48
Coding entries removed.	Thea Marie Cordero (b) (4)	27 Oct 2020 17:10:40
User entered 'TYLENOL liquid' reason for change:	Thea Marie Cordero (b) (4)	27 Oct 2020 17:10:40
Data Entry Error	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 23:31:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 23:31:35
Data point term sent to Coder	System	31 Aug 2020 23:30:58
User entered 'Tylenol'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:35
User entered 'No (N)'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:44:16
User entered 'SYMPTOMATIC COVID 19' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 22:17:46
User entered 'Febrile Illness'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:01
User closed query 'Per CDM: "Dose per administration" = "1 DOSE" and "Dose unit" = "2-3 TEASPOONS". Please update "Dose unt" = "TEASPOONS" and the "Dose per administration" with the corresponding numerical value (e.g. 2-3). Please review and reconcile. Thank you. ' (Site from DM).		07 Nov 2020 20:43:53
Query 'Per CDM: "Dose per administration" = "1 DOSE" and "Dose unit" = "2-3 TEASPOONS". Please update "Dose unt" = "TEASPOONS" and the "Dose per administration" with the corresponding numerical value (e.g. 2-3). Please review and reconcile. Thank you. ' answered with 'Data updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 15:47:57
User entered '2-3' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 15:46:54
User opened query 'Per CDM: "Dose per administration" = "1 DOSE" and "Dose unit" = "2-3 TEASPOONS". Please update "Dose unt" = "TEASPOONS" and the "Dose per administration" with the corresponding numerical value (e.g. 2-3). Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:41:49
User entered '1 dose' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:10:40
User entered '1000'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:03
User entered 'Other (OTHER)' reason for change:	Thea Marie Cordero	27 Oct 2020 17:10:40
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:06
User entered 'TEASPOONS' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 15:46:54
User entered '2-3 TEASPOONS' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 17:13:09
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	Thea Marie Cordero	27 Oct 2020 17:12:08
User entered '2-3 teaspoon' reason for change: Data Entry Error	System	27 Oct 2020 17:12:08
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4)	27 Oct 2020 17:10:40
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:47
User entered 'once daily (QD)' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Oct 2020 17:12:08
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:32:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 23:32:30
User entered 'as needed (PRN)' reason for change: New Information	Coni Cheesman (b) (4)	31 Aug 2020 23:32:30
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 23:30:21
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:49
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:51
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:08
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:12
User entered '29 Aug 2020'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:14
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:19
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:12:08
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:21:20
User entered '30 Aug 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:12:08
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:44:16
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please clarify.' answered with 'Data updated' (Site from DM).	Shetel Anassi (b) (4)	06 Nov 2020 18:52:14
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 18:52:06
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:18:30
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:30:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User entered '1'	System	27 Oct 2020 17:12:08
User entered empty.	System	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User entered '1'	System	27 Oct 2020 17:12:08
User entered empty.	System	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:12
User entered '804 (804)'	System	27 Oct 2020 17:12:08
User entered empty.	System	31 Aug 2020 23:30:21

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 19:27:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:24:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:24:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:58:48
Data point term sent to Coder	System	10 Nov 2020 17:22:47
User closed query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	10 Nov 2020 17:22:28
Query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'addressed' (Site from System).	Sandra Francisco (b) (4) (b) (4)	10 Nov 2020 17:22:28
Data point term sent to Coder	System	10 Nov 2020 17:19:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

Name of Medication

Audit	User	Time (GMT)
User entered 'NYQUIL COLD AND FLU (acetaminophen 500mg, doxylamine succinate 6.25 mg, dextromethorphan HBr 15mg)' reason for change: New Information	Sandra Francisco (b) (4)	10 Nov 2020 17:19:17
Data point term sent to Coder	System	10 Nov 2020 17:18:39
DataPoint Un-verified.	Sandra Francisco (b) (4)	10 Nov 2020 17:18:29
Coding entries removed.	(b) (4)	
	Sandra Francisco (b) (4)	10 Nov 2020 17:18:29
	(b) (4)	
User entered 'NYQUIL cold and flu' reason for change: New Information	Sandra Francisco (b) (4)	10 Nov 2020 17:18:29
User opened query 'For coding purposes, references indicate different formulations for NYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	(b) (4)	
	Coder Import (b) (4)	06 Nov 2020 19:59:23
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 20:25:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 20:25:44
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 20:25:04
Coding entries removed.	Thea Marie Cordero	29 Oct 2020 20:24:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:45:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 17:01:29
	(b) (4)	

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Thea Marie Cordero (b) (4)	27 Oct 2020 17:01:29 27 Oct 2020 17:00:20 27 Oct 2020 17:00:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:55:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Chanei Henry (b) (4) (b) (4)	08 Sep 2020 22:55:56 08 Sep 2020 22:55:14 08 Sep 2020 22:54:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 23:33:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Nyquil'	Coder Import (b) (4) (b) (4) System Coni Cheesman (b) (4)	31 Aug 2020 23:33:36 31 Aug 2020 23:33:01 31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:45:46
User entered 'No (N)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:17:52
User closed query 'Please update indication to match AE of Symptomatic COVID 19.' (Site from CRA).		09 Nov 2020 22:17:50
Query 'Please update indication to match AE of Symptomatic COVID 19.' answered with 'UPDATED' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:25:07
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:24:53
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.	(b) (4), (b) (6)	29 Oct 2020 08:11:37
' (Site from DM).		
User opened query 'Please update indication to match AE of Symptomatic COVID 19.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:46:09
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.	Thea Marie Cordero (b) (4)	27 Oct 2020 17:00:17
' answered with 'Updated' (Site from DM).		
User entered 'febrile illness' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:00:10
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.	(b) (4), (b) (6)	02 Oct 2020 10:41:31
' (Site from DM).		
User entered 'Nasal Congestion' reason for change: Data Entry Error	Chanei Henry (b) (4)	08 Sep 2020 22:54:47
User entered 'Febrile Illness'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:18:02
User closed query 'Please update dose and unit to 2-3 and teaspoons.' (Site from CRA).		09 Nov 2020 22:17:56
Query 'Please update dose and unit to 2-3 and teaspoons.' answered with 'UPDATED' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:25:15
User entered '2-3' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:24:53
User opened query 'Please update dose and unit to 2-3 and teaspoons.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:46:33
User entered '1 dose' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:08:27
User entered 'other' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:07:57
User entered '1'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:18:04
User entered 'Other (OTHER)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:18:05
User closed query 'Per CDM: Please remove "2-3" from the "Dose unit" as it is reflected in the "Dose per administration". Thank you.' (Site from DM). Query 'Per CDM: Please remove "2-3" from the "Dose unit" as it is reflected in the "Dose per administration". Thank you.' answered with 'Data updated' (Site from DM).	Shetel Anassi (b) (4)	07 Nov 2020 20:44:28
User entered 'TEASPOONS' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 15:48:25
User opened query 'Per CDM: Please remove "2-3" from the "Dose unit" as it is reflected in the "Dose per administration". Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:48:17
User entered '2-3 teaspoons' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	06 Nov 2020 15:43:08
User entered 'Unknown'	Coni Cheesman (b) (4)	27 Oct 2020 17:05:16
		31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:46:39
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	27 Oct 2020 17:06:20
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	27 Oct 2020 17:06:20
User entered 'once daily (QD)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:06:20
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	27 Oct 2020 17:05:16
User entered 'once (ONCE)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:05:16
User entered 'as needed (PRN)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:46:40
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:46:42
User entered 'Oral (ORAL)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:46:58
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:00
User entered '29 Aug 2020'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:01
User entered '0'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:02
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:05:16
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:35:10
User closed query 'Per comments in source from narrative, subject only took Nyquil on 29Aug20. Please review and update.' (Site from CRA).		09 Nov 2020 22:18:15
Query 'Per comments in source from narrative, subject only took Nyquil on 29Aug20. Please review and update.' answered with 'UPDATED' (Site from CRA).	Thea Marie Cordero (b) (4)	29 Oct 2020 20:25:22
User entered '29 Aug 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	29 Oct 2020 20:24:53
User opened query 'Per comments in source from narrative, subject only took Nyquil on 29Aug20. Please review and update.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:47:57
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:05
User entered '30 Aug 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Oct 2020 17:05:16
User entered empty.	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 22:18:20
DataPoint Un-verified.		28 Oct 2020 21:47:31
DataPoint Verified.		28 Oct 2020 21:47:07
User entered 'No (N)'	Coni Cheesman (b) (4)	31 Aug 2020 23:32:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered '1'	System	27 Oct 2020 17:06:20
User entered empty.	System	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered '1'	System	27 Oct 2020 17:06:20
User entered empty.	System	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:30:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:13:16
User entered '804 (804)'	System	27 Oct 2020 17:06:20
User entered empty.	System	31 Aug 2020 23:32:08

US3862050

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:30:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'No (N)' reason for change: New Information DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4) Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 20:54:32 18 Nov 2020 20:46:15
User entered 'Yes (Y)' reason for change: Data Entry Error DataPoint Verified.	Shetel Anassi (b) (4) (b) (4) (b) (4), (b) (6)	18 Nov 2020 20:46:15 10 Nov 2020 16:22:12
User closed query 'Per CDM: E-Diary Temp Day Timepoint Day 6 form indicates medication was taken to treat pain or fever. As per CCGs, kindly verify data and record this information onto the appropriate AE (Covid-19) and ConMed forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:14:01
Query 'Per CDM: E-Diary Temp Day Timepoint Day 6 form indicates medication was taken to treat pain or fever. As per CCGs, kindly verify data and record this information onto the appropriate AE (Covid-19) and ConMed forms. Thank you.' answered with 'Con med recorded' (Site from DM).	Chanei Henry (b) (4) (b) (4)	10 Sep 2020 01:00:24
User opened query 'Per CDM: E-Diary Temp Day Timepoint Day 6 form indicates medication was taken to treat pain or fever. As per CCGs, kindly verify data and record this information onto the appropriate AE (Covid-19) and ConMed forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 22:48:52
User entered 'No (N)' reason for change: Data Entry Error User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 13:35:23 03 Sep 2020 13:35:07

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Visit 2 Day 29 (VISIT2)'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '21 Sep 2020'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'Still on Convalescent period'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered 'I'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:30:28

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User entered '0'	Thea Marie Cordero (b) (4)	17 Nov 2020 18:07:50

US3862050

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:30:28

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:49:22
User closed query 'Per source and IRT, discontinuation occurred on 01Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 21:49:16
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:32
Query 'Per source and IRT, discontinuation occurred on 01Sep20. Please update.' answered with 'updated ' (Site from CRA).	Sandra Francisco (b) (4)	23 Nov 2020 20:55:39
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' answered with 'updated per source and IRT' (Site from DM).	Sandra Francisco (b) (4)	23 Nov 2020 20:55:34
User entered '1 Sep 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	23 Nov 2020 20:55:28
User opened query 'Per source and IRT, discontinuation occurred on 01Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:41:06
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:12:47

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:30:28

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	18 Nov 2020 20:50:35
User entered '01 Sep 2020'	Sandra Francisco (b) (4)	10 Nov 2020 17:24:55

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:30:28

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:49:11
User closed query 'Per source, discontinuation was due to AE #1 - please update accordingly on this page for accurate reporting purposes.' (Site from CRA).		01 Feb 2021 21:49:08
Query 'Per source, discontinuation was due to AE #1 - please update accordingly on this page for accurate reporting purposes.' answered with 'updated to reflect source per monitor's request' (Site from CRA).	Sandra Francisco (b) (4)	23 Nov 2020 20:56:36
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4)	23 Nov 2020 20:56:19
User opened query 'Per source, discontinuation was due to AE #1 - please update accordingly on this page for accurate reporting purposes.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:41:57
User entered 'Due to SARS-COV-2 (COVID)'	Sandra Francisco (b) (4)	10 Nov 2020 17:24:55

US3862050

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:30:28

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:09:06
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:09:51
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'data had been entered as requested by query. (AE#1)' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:59:36
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 19:58:53
User entered 'AE#1' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Mar 2021 19:58:53
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:22:04
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 21:49:19
User entered '#01' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	23 Nov 2020 20:56:19
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:51:24
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	18 Nov 2020 20:51:24
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:51:08
User entered 'USA-US121-2020-MRNA-1273-P301000001-Positive Test' reason for change: Data Entry Error	Shetel Anassi (b) (4)	18 Nov 2020 20:51:08

US3862050

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:30:28

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Sandra Francisco (b) (4)	10 Nov 2020 17:24:55
	(b) (4)	

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'USA-US121-2020-MRNA-1273-P301000001'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Hana'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'El Sahly'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'One Baylor Plaza'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Houston'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30
	(b) (4)	

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'TX'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered '77030'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:57
User entered 'US' (non-conformant).	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 19:00:25
User entered '2'	System	27 Oct 2020 15:46:42
User entered '1'	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'USA-US121-2020-MRNA-1273-P301000001'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Hana'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'El Sahly'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'One Baylor Plaza'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Houston'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'TX'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered '77030'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:57
User entered 'US' (non-conformant).	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 19:00:25
User entered '2'	System	27 Oct 2020 15:46:42
User entered '1'	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:30:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
User entered '10/Sep/2020 12:01'	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:30:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
User entered 'I'		10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'USA-US121-2020-MRNA-1273-P301000001'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Hana'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'El Sahly'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'One Baylor Plaza'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30
	(b) (4), (b) (6)	

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Houston'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'TX'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered '77030'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:57
User entered 'US' (non-conformant).	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 19:00:25
User entered '2'	System	27 Oct 2020 15:46:42
User entered '1'	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:30:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
User entered '27/Oct/2020 11:46'	System	27 Oct 2020 15:46:42

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:30:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:00:12
DataPoint Verified.		10 Nov 2020 02:32:21
User entered 'I'		27 Oct 2020 15:46:42

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'USA-US121-2020-MRNA-1273-P301000001'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		10 Sep 2020 16:01:00
User entered 'No (N)'	System	10 Sep 2020 15:57:55

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Hana'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'El Sahly'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'One Baylor Plaza'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'Houston'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30
	(b) (4), (b) (6)	

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered 'TX'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: User entered empty.	System	14 Sep 2020 22:07:26
User entered '77030'	Coni Cheesman (b) (4)	10 Sep 2020 18:08:30

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:21
Reviewed for Safety.		27 Oct 2020 15:46:18
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:57
User entered 'US' (non-conformant).	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 12 Aug 2021 13:30:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 19:00:25
User entered '2'	System	27 Oct 2020 15:46:42
User entered '1'	System	10 Sep 2020 16:01:09

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:30:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:49:13
User entered '19/Nov/2020 14:00'	System	19 Nov 2020 19:00:25

US3862050

Folder: SAE USA-US121-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:30:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:49:15
User entered 'I'		19 Nov 2020 19:00:25